Supreme Court, U.S.
FILED
DEC 6 - 2010
OFFICE OF THE CLERK

No. 10-

10-762

IN THE

Supreme Court of the United States

LOUISIANA WHOLESALE DRUG CO., INC., CVS PHARMACY, INC., RITE AID CORPORATION, ARTHUR'S DRUG STORE, INC.,

Petitioners,

v.

BAYER AG, BAYER CORP, formerly doing business as Miles Inc., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., WATSON PHARMACEUTICALS, INC., BARR LABORATORIES, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

BRUCE E. GERSTEIN
GARWIN GERSTEIN & FISHER LLP
1501 Broadway, Suite 1416
New York, NY 10036
(212) 398-0055

DAVID F. SORENSEN
BERGER & MONTAGUE, P.C.
1622 Locust Street
Philadelphia, PA 19103
(215) 875-3000

Counsel for Petitioner Louisiana Wholesale Drug Co., Inc.

STEVE D. SHADOWEN
Counsel of Record
MONICA L. REBUCK
HANGLEY ARONCHICK SEGAL & PUDLIN
30 N. Third Street, Suite 700
Harrisburg, PA 17101
(717) 364-1030
sshadowen@hangley.com

Counsel for Petitioners CVS Pharmacy, Inc. and Rite Aid Corporation

TIMOTHY D. BATTIN
STRAUS & BOIES, LLP
4041 University Drive
Fairfax, VA 22030
(703) 764-8700

Counsel for Petitioner Arthur's Drug Store, Inc.

233489

QUESTION PRESENTED

The Hatch-Waxman Act provides a pathway and financial incentives for a manufacturer of generic drugs to enter the market by obtaining a judicial determination that the brand drug maker's patent is invalid or not infringed. Brand firms can prevent or delay generic entry by paying the generics to forgo judicial review of the patents. In the case below, the Second Circuit held that, absent fraud on the patent office or sham litigation, such payments do not violate the Sherman Act, however weak the patent and even if the agreement delays generic entry until the patent expires.

The question presented is whether, absent patent fraud or sham litigation, a brand drug maker's substantial payment to a competing generic drug maker to forgo judicial testing of the patent and restrict entry is per se lawful under the Sherman Act.

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

Pursuant to Supreme Court Rule 14.1(b), Petitioners state that all parties to the proceedings below appear in the caption of the case on the cover page.[1]

Pursuant to Supreme Court Rule 29.6, Petitioners state that Petitioner Louisiana Wholesale Drug Company, Inc. does not have a parent corporation and no publicly held corporation owns 10% or more of its stock. Petitioner CVS Pharmacy, Inc. is a wholly-owned subsidiary of CVS Caremark Corporation, a publicly traded corporation. No publicly held corporation owns 10% or more of CVS Caremark Corporation's stock. Petitioner Rite Aid Corporation is a publicly traded corporation. The Jean Coutu Group (PJC), Inc. is the only publicly held corporation that owns 10% or more of Rite Aid Corporation's stock. Petitioner Arthur's Drug Store, Inc. does not have a parent corporation and no publicly held corporation owns 10% or more of its stock.

---

1. The Second Circuit transferred one of three consolidated appeals, 05-2863, to the Federal Circuit on November 7, 2007. Although the transferred appellants remained in the Second Circuit caption, they were not parties to the Second Circuit appeal at the time the decision was rendered. The transferred appellants were Arkansas Carpenters Health and Welfare Fund, Maria Locurto, Paper, Allied-Indus, United Food and Commercial Workers Union-Employer, Sol Lubin, Ann Stuart and Linda K. McIntrye.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT	ii
TABLE OF CONTENTS	iii
TABLE OF APPENDICES	v
TABLE OF CITED AUTHORITIES	vi
OPINIONS BELOW	1
JURISDICTION	1
STATUTORY PROVISIONS INVOLVED	1
INTRODUCTION	2
STATEMENT OF THE CASE	6
REASONS FOR GRANTING THE PETITION	13
I. The Court Should Grant Review Because the Circuit Courts Are Divided Over the Standard for Evaluating Whether Exclusion Payments Are Anticompetitive	13

Table of Contents

Page

II. The Court Should Grant Review Because the Second Circuit's Standard Conflicts with This Court's Precedents 23

III. The Court Should Grant Review Because This Case Is the Right Vehicle to Resolve This Recurring Issue of Enormous Public Importance 33

CONCLUSION 36

TABLE OF APPENDICES

APPENDIX A — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT DATED SEPTEMBER 7, 2010 ..... 1a

APPENDIX B — DECISION OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT DECIDED APRIL 29, 2010 CORRECTED JUNE 17, 2010 ..... 9a

APPENDIX C — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT, EASTERN DISTRICT OF NEW YORK DATED MARCH 31, 2005 ..... 36a

APPENDIX D — PERTINENT TEXT OF RELEVANT STATUTES 111a

TABLE OF CITED AUTHORITIES

Page

CASES

Andrx Pharm. Inc. v. Biovail Corp. Int'l,
256 F.3d 799 (D.C. Cir. 2001), *cert. denied*,
535 U.S. 931 (2002) 4, 16, 17, 29

Bayer AG v. Schein Pharm., Inc.,
129 F. Supp. 2d 705 (D.N.J. 2001),
aff'd, 301 F.3d 1306 (Fed. Cir. 2002) 26

Blonder-Tongue Labs., Inc. v.
Univ. of Ill. Found.,
402 U.S. 313 (1971) 10, 14, 24, 25

Cardinal Chem. Co. v. Morton Int'l Inc.,
508 U.S. 83 (1993) 26

Chicago Bd. of Trade v. United States,
246 U.S. 231 (1918) 14

Copperweld Corp. v. Independence Tube Corp.,
467 U.S. 752 (1984) 32

eBay Inc. v. MercExchange, L.L.C.,
547 U.S. 388 (2006) 27

Eastman Kodak Co. v.
Image Tech. Servs., Inc.,
504 U.S. 451 (1992) 22

Cited Authorities

Page

Edward Katzinger Co. v. Chicago Metallic Mfg. Co., 329 U.S. 394 (1947) 2, 24, 26

Federal Trade Comm'n v. Superior Court Trial Lawyers Ass'n, 493 U.S. 411 (1990) 31

Illinois Brick Co. v. Illinois, 431 U.S. 720 (1977) 33

In re Androgel Antitrust Litig., 687 F. Supp. 2d 1371 (N.D. Ga. 2010) 34

In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharm., Inc. v. Kroger Co.*, 543 U.S. 939 (2004) 4, 15, 16

In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied sub nom. Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, 129 S. Ct. 2828 (2009) 8, 20, 21

In re K-Dur Antitrust Litig., No. 01-1652, 2009 WL 508869 (D.N.J. Feb. 6, 2009) 20, 35

Cited Authorities

Page

In re Schering-Plough Corp.,
F.T.C. Docket No. 9297, 2003 WL 22989651
(F.T.C. Dec. 8, 2003), *rev'd, Schering-Plough Corp. v. Federal Trade Comm'n*, 402 F.3d 1056
(11th Cir. 2005), *cert. denied*, 548 U.S. 919
(2006) 17, 18

In re Tamoxifen Citrate Antitrust Litig.,
466 F.3d 187 (2d Cir. 2006), *cert. denied sub nom. Joblove v. Barr Labs, Inc.*,
551 U.S. 1144 (2007) ..... *passim*

In re Terazosin Hydrochloride Antitrust Litig.,
352 F. Supp. 2d 1279 (S.D. Fla. 2005) 19, 23

King Drug Co. of Florence, Inc. v. Cephalon, Inc.,
702 F. Supp. 2d. 514 (E.D. Pa. 2010) 35

Lear, Inc. v. Adkins,
395 U.S. 653 (1969) 2, 10, 25, 26

Medimmune, Inc. v. Genentech, Inc.,
549 U.S. 118 (2007) 26

Mova Pharm. Corp. v. Shalala,
140 F.3d 1060 (D.C. Cir. 1998) 29, 30

Nutrition 21 v. United States,
930 F.2d 867 (Fed. Cir. 1991) 29

Cited Authorities

Page

Palmer v. BRG of Georgia, Inc.,
498 U.S. 46 (1990) 14, 31

Precision Instrument Mfg. Co. v. Automotive Maint. Mach. Co.,
324 U.S. 806 (1945) 24

Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.,
508 U.S. 49 (1993) 31

Schering-Plough Corp. v. Federal Trade Comm'n,
402 F.3d 1056 (11th Cir. 2005),
cert. denied, 548 U.S. 919 (2006) 19, 20

United States v. Addyston Pipe & Steel Co.,
85 F. 271 (6th Cir. 1898), *aff'd*,
175 U.S. 211 (1899) 30

United States v. Glaxo Group Ltd.,
410 U.S. 52 (1973) 24

United States v. Microsoft Corp.,
253 F.3d 34 (D.C. Cir. 2001) (en banc) 31

United States v. Singer Mfg. Co.,
374 U.S. 174 (1963) 32

United States v. Topco Assocs., Inc.,
405 U.S. 596 (1972) 30, 31

Cited Authorities

Page

Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004) 5, 18

Walker Process Equip., Inc. v. Ford Mach. & Chem. Corp., 382 U.S. 172 (1965) 31

STATUTES

Sup. Ct. R. 14.1(b) ii

Sup. Ct. R. 29.6 ii

15 U.S.C. § 1 1

21 U.S.C. §§ 355(j)(2) 3

21 U.S.C. § 355(j)(2)(A)(vii)(IV) 6

21 U.S.C. § 355(j)(5)(B)(iii) 15, 29

21 U.S.C. §§ 355(j)(5)(B)(iv) 3, 14, 28

35 U.S.C. §§ 1 et seq. 1

28 U.S.C. § 1254(1) i

35 U.S.C. § 271 (a) 28

35 U.S.C. § 282 5

Page

Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) 1, 2

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1101-1104, 1111-1118, 117 Stat. 2066, 2448-2464 (2003) 1, 4

OTHER CITED MATERIALS

148 CONG. REC. S7348 (daily ed. July 25, 2002) 4

John R. Allison and Mark Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q. J. 185 (1998) 22

C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629 (2009) 34, 35

C. Scott Hemphill, *Paying For Delay: Pharmaceutical Patent Settlement As A Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006) 30

Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (June 2003) 9, 10, 32

Cited Authorities

Page

Herbert Hovenkamp, et al., IP AND ANTITRUST, § 15.3 (2d ed. 2010) 26

Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. OF ECON. 391 (Summer 2003) 9, 10

XII Hovenkamp, ANTITRUST LAW ¶ 2030b (2d ed. 2005) 14, 31

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 9a-35a) is reported at 604 F.3d 98. The denial of the rehearing en banc (Pet. App. 1a-8a) is not yet published but is electronically reported at 2010 WL 3464382. The district court's order granting Respondents' summary judgment motions (Pet. App. 36a-110a) is reported at 363 F. Supp. 2d 514.

JURISDICTION

The judgment of the court of appeals was entered on April 29, 2010. Rehearing en banc was denied on September 7, 2010. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Relevant portions of the Sherman Antitrust Act, 15 U.S.C. § 1; Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. §§ 355, 360cc, 35 U.S.C. §§ 156, 271, 282) (the "Hatch-Waxman Act" or the "Act"); the Patent Act, 35 U.S.C. §§ 1 et seq.; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1101-1104, 1111-1118, 117 Stat. 2066, 2448-2464 (2003) (the "Medicare Modernization Act"), are set out in an appendix to this petition.

INTRODUCTION

This case involves one of the most controversial business practices in the United States in one of the most important segments of our economy. Makers of branded pharmaceuticals are today routinely — 15 to 20 agreements every year — paying generic drug manufacturers not to challenge the validity of pharmaceutical patents and to delay entering the market. These agreements are annually costing consumers and taxpayers billions of dollars.

This Court has repeatedly "emphasiz[ed] the necessity of protecting our competitive economy by keeping open the way for interested persons to challenge the validity of patents which might be shown to be invalid." *Edward Katzinger Co. v. Chicago Metallic Mfg. Co.*, 329 U.S. 394, 400 (1947). The Second Circuit nevertheless held, contrary to the decisions of three other circuits and the views of the United States and the Federal Trade Commission, that, except in very limited circumstances, a pharmaceutical patentee may lawfully pay a generic drug manufacturer to forgo judicial testing of the patent's validity and stay out of the market. The Second Circuit's decision cannot be squared with those of other circuits or with this Court's prohibition on patentees "muzzling" those who otherwise would have an "economic incentive to challenge the patentability of an inventor's discovery." *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969).

This issue has repeatedly arisen, and continues to arise, in the context of patent litigation under the Hatch-Waxman Act. The Act was intended to promote

consumer welfare by balancing incentives for brand manufacturers to innovate against protections for consumers from unwarranted patent-based monopolies. The Act extends the effective term of pharmaceutical patents, but provides a financial incentive and streamlined procedures for manufacturers of generic drugs to enter the market by contesting patent validity or infringement in court. *See, e.g.*, 21 U.S.C. §§ 355(j)(2), 355(j)(5)(B)(iv). The Act relies on judicial testing in patent litigation to ensure that monopolies created by the extended patents are legitimate and thus in fact promote consumer welfare.

The increased patent litigation prompted by the Act revealed that many patent-based monopolies in the pharmaceutical industry are not in fact warranted. From 1992 to 2001 generics won 73% of the Hatch-Waxman cases litigated to conclusion. Pet. App. 31a n.7. With huge sums at stake, however, brand manufacturers began paying generics to concede patent validity and infringement and to waive or delay entry into the market. These payoffs from the brand to the generic have been referred to as "reverse payments," because they are cash payments from the plaintiff in the infringement action to the defendant, or as "exclusion payments" or "pay-for-delay payments" because they are made in exchange for forgoing judicial examination and restricting market entry.

In the late 1990s, the FTC obtained several consent decrees against manufacturers that had paid or accepted exclusion payments. The first courts of appeals to rule on the issue concluded that the payments are anticompetitive, explaining that the brand will pay the

generic only if the patent is otherwise not likely strong enough on its own to prevent the generic from entering the market: if the patent were strong enough to prevent entry, the brand "would not have paid [the generic] $89 million to effect what the patent and infringement suit had already accomplished." *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 915 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharm., Inc. v. Kroger Co.*, 543 U.S. 939 (2004); *see also Andrx Pharm. Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (same), *cert. denied*, 535 U.S. 931 (2002).

In the early 2000s, Congress considered legislation to prohibit exclusion payments, but stayed its hand after pharmaceutical industry representatives testified that remedial legislation was unnecessary because exclusion payment settlements "would have been violations of the antitrust laws and/or the patent laws whether the Hatch-Waxman Act existed or not." *See* Pet. App. 4a & n.4. Congress therefore solved the problem of exclusion payments — or so it thought — by amending the Act in 2003 to require manufacturers to report exclusion payment agreements to the FTC and the Department of Justice (*see* Medicare Modernization Act, Title XI, Subtitle B, §1112) so that the agencies could "do[] the right thing in taking enforcement actions against those who enter into anti-competitive agreements that violate our Nation's antitrust laws." 148 CONG. REC. S7348 (daily ed. July 25, 2002) (remarks of Sen. Hatch).

After Congress acted, however, the circuits became fractured on the standard for antitrust plaintiffs to prove that exclusion payments are anticompetitive, with courts affording the agreements increasingly lenient

antitrust treatment. The D.C. Circuit, Sixth Circuit, and the FTC had all concluded that the fact that the brand paid the generic was itself strong economic evidence that the payment resulted in less competition than the litigants themselves believed was likely to result from the patent litigation — otherwise, the brand would not have made the payment. The circuit split first developed when the Eleventh Circuit ruled that the lawfulness of an exclusion payment is determined by relitigating the patent issues as part of the antitrust case. *See Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004). The current three-way split occurred when a panel majority of the Second Circuit relied on the Patent Act's rebuttable presumption of patent validity (35 U.S.C. § 282) to conclude that, absent proof that the patent was obtained by fraud or the patent suit was a sham, the court analyzing the antitrust claim must conclusively presume that the brand manufacturer would have won the underlying patent litigation, and therefore that the exclusion payment was not anticompetitive. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006), *cert. denied sub nom. Joblove v. Barr Labs, Inc.*, 551 U.S. 1144 (2007).

The *Tamoxifen* panel acknowledged that, if exclusion payments are permissible, brands will use them routinely to protect even "fatally weak" patents. *Id.* at 211. Indeed, after the *Tamoxifen* decision in late 2005, 20 of the next 27 settlements between brands and generics used exclusion payments to restrict generic entry. Pet. App. 33a. By protecting unwarranted patent-based monopolies from judicial review, these exclusion payment settlements have already cost consumers and

taxpayers more than $12 billion, and threaten to cost another $3.5 billion annually. Pet. App. 5a & n.6.

In the present case, the brand paid the generic $398 million to acknowledge patent validity and stay out of the market for all but six months of the remaining seven-year patent term. When the case reached the Second Circuit, the United States, the FTC, 36 State Attorneys General, 86 professors of law or economics, and the major consumer rights organizations filed briefs asserting that the circuit's liability standard is unduly lenient and is causing enormous consumer harm. The Second Circuit panel here unanimously concluded that the circuit's *Tamoxifen* standard should be revisited, but that the panel was nevertheless bound to follow it. Pet. App. 26a, 31a-35a.

The Court should grant review to resolve the circuit split, reject the Second Circuit standard, require compliance with this Court's precedents that favor judicial testing of patent validity, and restore the Hatch-Waxman Act balance by prohibiting brand manufacturers from paying competitors to forgo judicial examination of patents and thereby preserve unwarranted monopolies.

STATEMENT OF THE CASE

Respondent Barr Laboratories submitted a Paragraph IV Certification[1] under the terms of the

1. Such a Certification asserts that the patent on the brand drug "is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug." 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Hatch-Waxman Act, asserting that the patent on Respondent Bayer Corporation's ("Bayer") best-selling antibiotic, Cipro, was invalid and unenforceable. Pet. App. 40a. In Bayer's ensuing patent suit, its motions for summary judgment were denied and the case was scheduled for trial. *Id.* at 41a. Bayer knew there was a "substantial question" as to the patent's validity, and Barr[2] had additional significant defenses of unenforceability due to inequitable conduct. If Barr won the patent case, the opening of the market to generic competition would have generated enormous savings for consumers. *Id.* at 50a. Bayer estimated that a loss in the patent case and the ensuing price competition would cause it to lose more than $1.6 billion in monopoly profits. *Id.*

Shortly before trial, Bayer and Barr settled. In exchange for Barr's agreement to confess judgment and stay out of the market for all but six months of the remaining patent term, Bayer agreed to pay Barr quarterly payments totaling $398 million. *Id.* at 42a. Alternatively, Bayer had the option to grant Barr a license to enter the market for six of the remaining seven years — a license that would have brought hundreds of millions of dollars in savings to consumers. *See id.* at 42a, 50a. Rather than permit this competition, Bayer elected under the agreement to pay Barr the $398 million, which was roughly one to two times the amount

2. Respondents Hoechst Marion Roussel and the Rugby Group, which was later acquired by Respondent Watson, contracted with Barr to share the patent litigation expenses and any resulting profits from sale of generic Cipro, and were also signatories to the challenged exclusion payment agreement. For convenience, we refer to Barr and HMR/Rugby collectively as "Barr."

Barr would have earned by winning the patent case and competing in the market.

Petitioners, direct purchasers of Cipro, filed claims against Bayer and Barr for money damages, asserting that the exclusion payment agreement violated Section 1 of the Sherman Act.[3] In opposition to Respondents' motions for summary judgment, and in support of their own motions for partial summary judgment, Petitioners offered evidence, under the rule of reason, that the six months of competition that resulted from the $398 million payment was less competition than was likely to have occurred absent the payment. This evidence included:

First, economic evidence that the payment resulted in less competition than Bayer and Barr themselves expected the patent litigation to yield, given their views of the patent's strength. If the exclusion payments did not bring less competition than both Bayer and Barr expected, one or both of them would have chosen to

3. The district court proceedings also included the claims of a putative class of indirect purchasers of Cipro. Those plaintiffs, unlike Petitioners, asserted a claim that Bayer committed fraud in obtaining the patent from the Patent and Trademark Office — a claim that the Second Circuit held "arises under" the patent laws and is thus within the exclusive appellate jurisdiction of the Federal Circuit. The Second Circuit transferred those plaintiffs' appeal to the Federal Circuit while retaining jurisdiction over Petitioners' appeals. Pet. App. 20a. The Federal Circuit affirmed the grant of summary judgment against those plaintiffs. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied sub nom. Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, 129 S. Ct. 2828 (2009). *See infra* at 20-21.

litigate rather than settle. *See* Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1758-59 (June 2003); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. OF ECON. 391, 394-95 (Summer 2003).

Second, this economic evidence was confirmed by the terms of Respondents' agreement, which provided that Bayer must give Barr either $398 million and a license to enter for six months, or a license to enter for six years. These alternative contract terms demonstrate "with unusual clarity" that exclusion payments buy the absence of competition that otherwise would likely have resulted from the patent case. Brief for the United States ("U.S. Br.") at 24 (2d Cir. July 6, 2009).

Third, deposition testimony confirmed that Barr demanded to receive in settlement an "overall value" commensurate with its view of the patent's strength. Barr demanded receipt of this value either through a license allowing it to compete in the market or through cash payments in exchange for not competing. Likewise, Bayer calculated how much to pay Barr based on a detailed expected-value analysis based on the patent's strength.

Petitioners did not — and do not — allege that it is unlawful for patent litigants to settle Hatch-Waxman cases. Litigants routinely and lawfully settle patent cases through licenses that permit the alleged infringer to enter the market before the patent expires. The patentee gauges the patent's strength and offers to give a license for, say, five years of the remaining ten-year term. The alleged infringer also gauges the patent's strength and may accept the five-year license.

These licensed-entry settlements, like exclusion payment settlements, avoid authoritative judicial testing of patents. The former generally do not violate the Sherman Act, however, because judicial testing of patents is not an end in itself, but a means of eliminating unwarranted patent-based monopolies. *See, e.g.*, *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 343 (1971); *Lear*, 395 U.S. at 670. Absent an exclusion payment, settlement via a license eliminates the monopoly to the extent dictated by the patent's strength: competition occurs, and consumers benefit, for a period of time determined solely by the patent litigants' respective views of the patent's strength. Licensed entry, without exclusion payments, thus mirrors the risk-adjusted outcome of the patent litigation. *See* Hovenkamp, *Anticompetitive Settlement*, 87 MINN. L. REV. at 1758-59; Shapiro, *Antitrust Limits*, 34 RAND J. OF ECON. at 397-99.

Exclusion payment settlements are entirely different. If the patent's strength would have dictated, say, a five-year license, the generic will accept instead an exclusion payment that gives it at least five years' worth of forgone profits (or will accept a fig-leaf six month license plus a payment equal to at least 4.5 years' profit). The brand and generic avoid five years of expected competition and divide the eliminated consumer savings between themselves. In contrast, limiting the "coin" of settlement to licensed entry ensures that the generic will agree to stay out of the market for a period of time determined solely by the strength of the patent, and not by receipt of a share of the preserved monopoly profits.

The district court here found "quite powerful" the basic economic fact that "the greater the chance a court would hold the patent invalid, the higher the likelihood that the patentee will seek to salvage a patent by settling with an exclusion payment." Pet. App 77a-78a. The court nevertheless granted Respondents' motions for summary judgment, holding that exclusion payments are lawful under Section 1 of the Sherman Act unless the antitrust claimant proves that the underlying patent was procured by fraud or that the patent litigation was a sham. *Id.* at 79a. This result was "compelled by the presumption of validity Congress accorded patents." *Id.* at 109a. According to the court, the rebuttable presumption of validity gives the patentee "the right to exclude competition entirely for ciprofloxacin for the term of the patent," including the right to pay the alleged infringer to concede validity and stay out of the market. *Id.* at 53a.

While the district court's ruling was on appeal in the Second Circuit, that court decided another exclusion payment case — *Tamoxifen*. A divided panel in *Tamoxifen* relied heavily on the *Cipro* district court's analysis and likewise concluded that exclusion payments are lawful unless the patent was obtained by fraud or the patent claim was a sham. *Tamoxifen*, 466 F.3d at 213. The panel majority acknowledged the "troubling dynamic" of permitting exclusion payments that "inevitably protect patent monopolies that are, perhaps, undeserved," and that, indeed, protect "fatally weak" patents. *Id.* at 211, 212. But, said the majority, the rebuttable presumption of validity requires this result: in paying the generic, the brand is merely "protect[ing] that to which it is presumably entitled." *Id.* at 208.

In this case, a Second Circuit panel affirmed the grant of summary judgment against Petitioners solely because the panel "is bound by *Tamoxifen*." Pet. App. 31a. The panel enumerated "several reasons why this case might be appropriate for reexamination," including the argument that the "*Tamoxifen* standard inappropriately permits patent holders to contract their way out of the statutorily imposed risk that patent litigation could lead to invalidation of the patent while claiming antitrust immunity for that private contract." *Id.* at 31a-32a (quoting U.S. Br. at 14-15). Moreover, permitting patentees to prop up weak patents by shielding them from judicial scrutiny "offers no protection to the public interest in eliminating undeserved patents." *Id.* The panel also acknowledged the argument "that *Tamoxifen* runs afoul of the purpose of the Hatch-Waxman Act" by undermining its "incentive . . . for generic manufacturers to challenge presumptively valid patents." *Id.* at 30a.

Judge Pooler's dissent from the subsequent denial of Petitioners' request for en banc consideration elaborated on the panel's disagreement with *Tamoxifen*.[4] The "presumption of patent validity is simply a procedural device that assigns burdens in litigation challenging the validity of an issued patent. There is no basis for treating that presumption as virtually conclusive and allowing it to serve as a substantive basis

4. The two senior judges on the panel could not participate in deciding whether to grant rehearing en banc, but Judge Pooler reported that "the panel opinion endorses the views expressed in" her dissent from the denial of en banc rehearing. Pet. App. 3a n.1.

to limit the application of the Sherman Act." *Id.* at 6a (quoting U.S. Br. at 6-7). The Second Circuit standard is also "plainly inconsistent with the stated purpose of the Hatch-Waxman Act, which is to encourage patent challenges as a way of increasing consumer access to low-cost drugs." Pet. App. 6a. The standard "unambiguously deserves reexamination," the "'enormous importance' of the issues that this case raises is beyond dispute," and the Supreme Court should "resolve the conflict among the Courts of Appeals." *Id.* at 8a.

REASONS FOR GRANTING THE PETITION

I. The Court Should Grant Review Because the Circuit Courts Are Divided Over the Standard for Evaluating Whether Exclusion Payments Are Anticompetitive.

The circuits are split three ways over the proper standard for determining whether an exclusion payment is anticompetitive. The Sixth and D.C. Circuits hold that the fact that the brand made a payment to the generic is substantial economic evidence that, in the litigants' view, the patent was not strong enough on its own to prevent competition. The Eleventh Circuit determines whether an exclusion payment is anticompetitive by requiring that the patent issues be relitigated as part of the antitrust case. The Second Circuit relies on the rebuttable presumption of patent validity, unless there was fraud on the PTO or sham litigation, to conclude that the patentee would have won the patent case and therefore the exclusion payment is not anticompetitive.

A plaintiff makes a prima facie case of anticompetitive conduct under Section 1 of the Sherman Act by producing evidence that the challenged agreement resulted in less competition than was likely to occur absent the agreement. *Chicago Bd. of Trade v. United States*, 246 U.S. 231, 240-41 (1918). The proper standard for determining whether exclusion payments are anticompetitive — whether they result in less competition than was otherwise likely to occur — must account for three statutory regimes: (1) the Sherman Act, which has long prohibited incumbent manufacturers from paying competitors not to enter a market, including when potential economic or legal barriers make it uncertain whether the competitor would have been successful in entering, *see, e.g., Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 48-49 (1990); XII Hovenkamp, ANTITRUST LAW ¶ 2030b at 213 (2d ed. 2005); (2) the Patent Act, which includes a rebuttable presumption of validity, but depends on judicial review to prevent unwarranted patent-based monopolies, *e.g., Blonder-Tongue Labs*, 402 U.S. at 343; and (3) the Hatch-Waxman Act, which includes a statutory incentive for generics to enter the market by means of contesting patent validity or infringement in court, 21 U.S.C. § 355(j)(5)(B)(iv). The circuit split is over the proper standard, given these statutory mandates, for an antitrust plaintiff to prove that an exclusion payment resulted in less competition than was likely to occur "but for" the payment.

Sixth Circuit/D.C. Circuit/FTC: The Sixth Circuit, D.C. Circuit, and the FTC have adopted the "patent strength" standard, which bases the but-for amount of competition on the patent litigants' own view of the likely outcome of the litigation, as reflected in their objective

conduct. The fact that the generic demanded and the brand agreed to make an exclusion payment is strong economic evidence that, in those litigants' own judgment, the patent was not otherwise strong enough to prevent earlier generic entry. The patent strength standard recognizes that exclusion payments are "naturally viewed as consideration for the generic's agreement to delay entry beyond the point that would otherwise reflect the parties' shared view of the likelihood that the patentee would ultimately prevail in the litigation." U.S. Br. at 22.

In *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), the court applied the patent strength standard where the brand paid the generic to stay out of the market pending resolution of the patent litigation (the Hatch-Waxman Act automatic 30-month stay of generic entry, 21 U.S.C. § 355(j)(5)(B)(iii), had expired). Thus, *Cardizem* arose in a different factual context than here — the exclusion payment in *Cardizem* was made in exchange for the generic forgoing judicial testing of the patent in a preliminary injunction proceeding, and staying out of the market until entry of a final and unappealable judgment. But the legal issue is the same — the proper legal standard for determining whether it is anticompetitive for the brand to pay the generic to forgo the relevant judicial examination (preliminary injunction or trial on the merits) and stay out of the market for the relevant period of time (until the case conclusion or for a defined period).

Recognizing that many litigated patents are found to be invalid or not infringed, the Sixth Circuit held that a brand's patent does not create an "'impenetrable' legal

impediment" to generic entry. 332 F.3d at 914. Instead, the generic's analysis of the patent's strength may or may not cause it to "unilaterally, and legally [refrain from] bring[ing] its generic product to a manifestly profitable market." *Id.* at 915. An exclusion payment alters the generic's unilateral calculation based on the patent's strength and results in less competition than otherwise would likely have occurred: if the "independent durability of [HMRI's] patent and the validity of its infringement claim" had been sufficient on their own to exclude the generic from the market, then the brand "would not have paid [Andrx] $89 million to effect what the patent and infringement suit had already accomplished." *Id.* at 915. "[I]t is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market." *Id.* at 908. The court upheld the grant of partial summary judgment to plaintiffs as to antitrust liability, concluding that the anticompetitive consequences of the payment were so clear that they not only satisfied plaintiffs' prima facie case, but rendered the agreement per se unlawful. *Id.*

Considering the same agreement that was at issue in *Cardizem*, the D.C. Circuit had earlier also relied on the patent strength standard in reversing the dismissal of the antitrust claims of another generic competitor whose entry was blocked by the HMRI/Andrx agreement. *Andrx Pharm.*, 256 F.3d at 799. The court held that the agreement caused antitrust injury — injury of the type the antitrust laws are designed to prevent — because:

> HMRI's ten million dollar quarterly payments were presumably in return for something that Andrx would not otherwise do, that is, delay marketing of its generic. Andrx's argument that any rational actor would wait for resolution of the patent infringement suit [before entering the market] is belied by the *quid* of HMRI's *quo*.

Id. at 813. An exclusion payment thus "harms consumers by slowing the introduction of lower priced products into the market and thwarts the intent of the Hatch-Waxman Amendments." *Id.* (quoting 54 Fed. Reg. 42,873, 42,882-83).

The FTC applied the same standard in an administrative proceeding in *In re Schering-Plough Corp.*, F.T.C. Docket No. 9297, 2003 WL 22989651 (F.T.C. Dec. 8, 2003), *rev'd, Schering-Plough Corp. v. Federal Trade Comm'n*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006). Evaluating an exclusion payment made in exchange for forgoing a final judicial decision on the merits, the FTC held that, "it is reasonable to assume that an agreed-on entry date [in an entry-license settlement], without cash payments, reflects a compromise of differing litigation expectations." *Id.* at 14. The fact that the patentee made a payment is economic evidence that the agreement resulted in less competition than the litigants themselves expected: "[i]f there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the

generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise." *Id.* Accordingly, evidence that the brand made a significant payment satisfied plaintiff's initial burden under the rule of reason. *Id.* at 15.

Eleventh Circuit: The Eleventh Circuit has expressly rejected the patent strength standard applied by the Sixth and D.C. Circuits and the FTC. *Valley Drug*, 344 F.3d at 1310. Instead, it determines the amount of but-for competition by engaging in an *ex-post* judicial determination of the patent issues as part of the antitrust case. *Id.* at 1312.

In *Valley Drug*, as in *Cardizem*, the 30-month stay had expired and the brand paid the generics to stay out of the market pending resolution of the patent case. The Eleventh Circuit held that antitrust analysis of exclusion payments requires "an identification of the protection afforded by the patents and the relevant law and consideration of the extent to which the Agreements reflect a reasonable implementation of these." *Id.* To determine whether it was anticompetitive for the brand to pay the generic not to try to enter the market before resolution of the patent case, "the provisions of this Agreement should be compared to the protections afforded by the preliminary injunction and stay mechanisms and considered in light of the likelihood of [the brand's] obtaining such protections. *Cf.* Hovenkamp at § 2046 ('some care must be taken to ensure that . . . the settlement . . . is not more anticompetitive than a likely outcome of the litigation')." 344 F.3d at 1312. On remand, the district court conducted an exhaustive analysis of the merits of the underlying patent case and

found the exclusion payments unlawful because "[t]he chance that the '207 patent would be held valid — an essential part of the equation for defining the legitimate exclusionary value of the patent — was not high as of [the date of the Agreement]." *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1298 (S.D. Fla. 2005).

The Eleventh Circuit subsequently reaffirmed this "patent relitigation" approach and applied it to an exclusion payment made in exchange for forgoing final adjudication of the patent. *Schering-Plough Corp. v. Federal Trade Comm'n*, 402 F.3d 1056, 1076 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006). In *Schering*, which was the appeal from the FTC's order finding the Schering-Upsher agreement unlawful under the patent strength standard, the court faulted the FTC for relying on *ex ante* economic evidence of the patent's strength rather than conducting an *ex post* judicial evaluation. According to the court, the FTC, "cavalierly dismissed our holding in *Valley Drug*, stating that [an *ex-post* judicial] determination on the merits of the underlying patent dispute was 'not supported by law or logic.'" *Id.* at 1068 n.18.[5] The court reaffirmed that the but-for amount of competition should be determined by an *ex-post* judicial determination of the patent issues: "a settlement cannot [lawfully] be more anticompetitive than litigation." *Id.* at 1075. "*Valley Drug* established the law in our Circuit. . . . This alone underscores the

5. Relying on the patent strength standard, the FTC complaint counsel had argued that relitigating the merits of the patent case was unnecessary, and so had offered no independent evidence that the patent was invalid or not infringed.

need [for the court in the antitrust case] to evaluate the strength of the patent." *Id.* at 1076.[6]

The Eleventh Circuit's standard is subject to criticism because of the potential complexity and inefficiency of relitigating patent issues in an antitrust case. Moreover, deferring the patent issues into the antitrust case is likely to result in a significant temporal extension of the monopoly — the appeal of the FTC's order against the Schering-Upsher agreement was not concluded until nine years after execution of the agreement, and private antitrust claims over the agreement are still pending. Equally troubling, the generics, which have expertise in challenging pharmaceutical patents, switch sides in the antitrust case: Upsher asserted in the patent case that Schering's infringement claim was so weak as to constitute a sham, then joined with Schering in the antitrust case to argue that the infringement claim was not a sham. *See In re K-Dur Antitrust Litig.*, No. 01-1652, 2009 WL 508869, at *30 (D.N.J. Feb. 6, 2009).

Second and Federal Circuits: The Second and Federal Circuits have expressly rejected the Sixth/D.C. Circuit patent strength standard and have refused to apply the Eleventh Circuit's relitigation standard. *See Tamoxifen*, 466 F.3d at 203-04, 213; *Ciprofloxacin*, 544 F.3d at 1337. They have instead conclusively presumed for purposes of the antitrust case that the patent was valid, and thus that no competition was likely to result

6. The Eleventh Circuit also reversed, on the record before it, the FTC's factual finding that the brand had made a payment to the generic. *Schering-Plough Corp.*, 402 F.3d at 1071.

from the patent litigation, unless the patent was obtained by fraud or the patent claim was a sham.

As noted above, the panel majority in *Tamoxifen* concluded that this sham litigation standard is required by the rebuttable presumption of patent validity. *Tamoxifen*, 466 F.3d at 213. The Second Circuit panel here unanimously disagreed with that conclusion but felt bound to adhere to *Tamoxifen*.

The Federal Circuit considered the same agreement at issue here, at the behest of indirect purchasers of Cipro whose appeal was transferred to that circuit.[7] The Federal Circuit concluded it was required to decide the case "[u]nder the law of the Second Circuit." *Ciprofloxacin*, 544 F.3d at 1332. The court held that the rebuttable presumption of validity required adoption of the sham litigation standard, reasoning that, "[a] settlement is not unlawful if it serves to protect that to which the patent holder is legally entitled — a monopoly over the manufacture and distribution of the patented invention. *In re Tamoxifen*, 466 F.3d at 208-09." *Ciprofloxacin*, 544 F.3d at 1337.[8]

The sham litigation standard is legally and factually insupportable. This Court has endorsed such a lenient antitrust standard only for a monopolist's unilateral, constitutionally protected conduct in petitioning the government to restrain competition. *See infra* at 32. That standard is wholly inappropriate for judging

7. *See supra* footnote 3.

8. We discuss *infra* at 33 the circumstances in which this Court declined to review the Federal Circuit's decision.

erstwhile competitors' joint conduct in withdrawing a patent dispute from judicial oversight and restraining competition by private agreement.

The sham litigation standard also ignores the commercial reality that, despite the rebuttable presumption of validity, nearly half of all litigated patents are found invalid, John R. Allison and Mark Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q. J. 185, 206 (1998), and that generics have won 73% of Hatch-Waxman cases, Pet. App. 31a n.17. Under the sham litigation standard, a patentee with merely a colorable claim, with, say, an 80% chance of *losing*, may lawfully pay the generic a share of the monopoly profits in exchange for staying out of the market. *Cf. Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 466-67 (1992) ("[l]egal presumptions that rest on formalistic distinctions rather than actual market realities are generally disfavored in antitrust law"). The rebuttable presumption of validity was designed merely to allocate burdens of proof in a patent litigation that determines *whether* the patent-based monopoly is legitimate, not to authorize the patentee to pay to prevent judicial review and thereby preserve the monopoly *regardless* of its legitimacy. As Judge Pooler noted:

> [E]ven though we are required to presume that Bayer's patent is valid, . . . "[t]he presumption of patent validity is simply a procedural device that assigns burdens in litigation challenging the validity of an issued patent. There is no basis for treating that presumption as virtually conclusive and

> allowing it to serve as a substantive basis to limit the application of the Sherman Act."

Pet. App. 6a (quoting U.S. Br. at 6-7). If upheld, the sham litigation standard "would essentially afford pioneer drug manufacturers an unbridled power to exclude others without regard to the strength of their patent rights." *Terazosin*, 352 F. Supp. 2d at 1298.

The Second Circuit's sham litigation standard conflicts with the patent relitigation standard of the Eleventh Circuit and with the patent strength standard of the Sixth and D.C. Circuits and the FTC. Under the sham litigation standard, exclusion payments are nearly per se lawful; under the patent strength standard, the fact that the brand made an exclusion payment is, at a minimum, sufficient evidence to satisfy the antitrust plaintiff's initial burden under the rule of reason, and, under the Sixth Circuit approach, renders the agreement per se unlawful. Shunning both of these standards, the Eleventh Circuit requires the patent issues to be litigated anew as part of the antitrust case. The conflict between the circuits is clear and wide.

II. The Court Should Grant Review Because the Second Circuit's Standard Conflicts with This Court's Precedents.

The Second Circuit has elevated the rebuttable presumption of validity into an ironclad right of patentees to exclude competition — a right enforceable by paying generics to forgo judicial examination of patent validity and stay out of the market. The Second Circuit's newly created right conflicts with two lines of this Court's cases.

Conflict With the Court's Patent Cases. The Second Circuit standard conflicts with this Court's patent cases, which emphasize that a patentee's right to exclude competitors is limited and qualified, and that "[i]t is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly." *United States v. Glaxo Group Ltd.*, 410 U.S. 52, 58 (1973) (citation omitted). "A patent by its very nature is affected with a public interest" because of its potentially "far-reaching social and economic consequences." *Precision Instrument Mfg. Co. v. Automotive Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). Consequently, the alleged infringer's right to challenge the patent's validity in court "is not only a private right to the individual, but it is founded on public policy, which is promoted by his making the defense, and contravened by his refusal to make it." *Edward Katzinger Co.*, 329 U.S. at 401 (citation omitted).

The Second Circuit asserted that it had safeguarded the public interest by limiting the exclusion effected by the brand's payments to the subject matter and temporal scope of the patent, assuming that the patent is valid. *Tamoxifen*, 466 F.3d at 213-14. But under this Court's precedents, the requirement that exclusion not exceed the subject matter or temporal scope of the patent is just "one obvious manifestation" of the public interest in patents. *Blonder-Tongue Labs*, 402 U.S. at 343. The Second Circuit ignored a second aspect of this interest — "[a] second group of authorities [that] encourage authoritative testing of patent validity." *Id.*

at 344.[9] Although patents carry a rebuttable presumption of validity, "Congress has from the outset chosen to impose broad criteria of patentability while lodging in the federal courts final authority to decide that question." *Id.* at 332.

Accordingly, this Court has repeatedly emphasized that judicial testing of patent validity is essential precisely because the issuance of a patent by the PTO was not intended to have — and does not have — the conclusive significance accorded by the Second Circuit:

> A patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office. Moreover, the legal conclusion is predicated on factors as to which reasonable men can differ widely. Yet the Patent Office is often obliged to reach its decision in an *ex parte* proceeding, without the aid of the arguments which could be advanced by parties interested in proving patent invalidity.

Lear, 395 U.S. at 670.

This Court has held, for example, that requiring patent licensees to continue paying royalties as a prerequisite to challenging patent validity would

9. We again note that this does not mean that litigants should be precluded from settling Hatch-Waxman patent cases. The purpose of judicial testing of patent validity is to protect consumers from unwarranted patent-based monopolies. Licensed entry settlements, unlike exclusion payment settlements, eliminate monopolies — and benefit consumers — to the extent dictated by the strength of the patent. *See supra* at 10.

impermissibly "muzzle[]" those who otherwise have an "economic incentive to challenge the patentability of an inventor's discovery." *Id.*; *see also Medimmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (federal courts have jurisdiction to decide patent validity even when parties are complying with license terms). Permitting brands to simply pay generics to forgo judicial testing of patents is the antithesis of "protecting our competitive economy by keeping open the way for interested persons to challenge the validity of patents which might be shown to be invalid." *Edward Katzinger Co.*, 329 U.S. at 400.

This Court also held that it is "inconsistent with the aims of federal patent policy" to permit patentees to "postpone the day of final judicial reckoning." *Lear*, 395 U.S. at 673; *see also Cardinal Chem. Co. v. Morton Int'l Inc.*, 508 U.S. 83, 101 n.24, 102 (1993) (prohibiting practice of vacating declaratory judgments of invalidity because it improperly "multipl[ies] the opportunities for holders of invalid patents" to try to enforce them and "prolongs the life of invalid patents"). Permitting the brand to pay the first generic challenger to forgo judicial review delays challenges by other generics. "The regulatory scheme for pharmaceutical patents [*i.e.*, the 30-month Hatch-Waxman stay of generic entry] means that by settling with an ANDA filer, a patent owner can delay entry by any other generic for three years or more." Herbert Hovenkamp, et al., IP AND ANTITRUST, §15.3 at 15-45 (2d ed. 2010). For example, here subsequent challengers to the Bayer patent did not even get to the summary judgment stage until over four years after the Bayer/Barr trial was to have begun. *See Bayer AG v. Schein Pharm., Inc.*, 129 F. Supp. 2d 705 (D.N.J. 2001), *aff'd*, 301 F.3d 1306 (Fed. Cir. 2002). And as is often

the case, this not only delayed, but also reduced the potency of, those subsequent challenges. Given the imminent expiration of the Bayer patent, the delayed subsequent challengers waived all fact-intensive defenses to Bayer's patent, with the result that the best defenses that Barr intended to pursue at trial have never been litigated. *See* Plaintiffs-Appellants' Brief at 15 (2d. Cir. May 5, 2008). *See also Tamoxifen*, 466 F.3d at 194 (exclusion payment settlement was contingent on vacatur of district court judgment finding patent invalid). The Second Circuit standard permits the patentee to buy multiple opportunities and to unfairly tilt the litigation landscape in the very ways this Court has condemned as against public policy.

The Second Circuit standard also disregards this Court's critical distinction between a patentee's substantive right to exclude competition and the limited, qualified remedies available to the patentee to enforce that right. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 392 (2006). The Court held that even after a final judgment finding infringement, the patentee is not automatically entitled to exclude the adjudged infringer, but instead must satisfy the traditional requirements for equitable relief. *Id.* at 392-93. Under *eBay*, even a patent judicially tested and found valid and infringed may not merit excluding competition; under the Second Circuit standard, wholly untested, exceedingly weak patents — all except those whose attempted enforcement would constitute a sham — merit excluding competition.

The Second Circuit standard is even less supportable when considered in light of the Hatch-

Waxman Act's statutory incentives for generics to enter the market through patent challenges. The Act provides that the first generic that challenges the patent can receive 180 days as the exclusive generic version of that product on the market. 21 U.S.C. § 355(j)(5)(B)(iv). This reward is valuable to the generic only if it enters the market and sells a low-price product to consumers. The statutory incentive was designed to bring consumer savings through generic entry, not to enrich generic firms that accept payments to forgo entry.

The Hatch-Waxman Act also precludes any notion that unreviewed patents grant an ironclad right to exclude competitors. The Act gives patentees a procedure to obtain automatic exclusion of generics — without the need to satisfy the criteria for a preliminary injunction — for up to 30 months.[10] After 30 months, however, the FDA is free to approve a generic drug for

10. The Second Circuit seemed to suggest that the Act's 30-month stay provision somehow makes exclusion payments "natural" because it prevents the generic from entering the market and amassing potential liability for infringement damages that the brand could use as a bargaining chip in settlement negotiations. *Tamoxifen*, 466 F.3d at 206-07. The idea seems to be that this reduced settlement leverage makes exclusion payments the only viable means of settling the case. But the Act does not require the brand to invoke the 30-month stay; the brand may instead renounce the stay and then try to collect damages for infringement. 35 U.S.C. § 271(a). Even when brands relinquish some settlement leverage in exchange for 30-month stays, the patent cases still can be settled without exclusion payments, and thus they "serve no obvious redeeming social purpose." Pet. App. 5a. The cases can be settled – and, until *Tamoxifen*, routinely were settled — through early-entry licenses. *See id.* at 33a.

marketing regardless of ongoing patent litigation and despite the rebuttable presumption of validity. *See* 21 U.S.C. § 355(j)(5)(B)(iii). After the 30 months, the patentee can obtain exclusion only by obtaining a preliminary injunction — a proceeding in which "the *patentee* carries the burden of showing likelihood of success on the merits with respect to the patent's validity." *Nutrition 21 v. United States*, 930 F.2d 867, 869 (Fed. Cir. 1991). Yet the Second Circuit relies on the rebuttable presumption of validity to justify the brand's obtaining the equivalent of an automatic, unreviewed, post-30-month permanent injunction through the expedient of sharing some of the monopoly profits with the generic.

Exclusion payments are plainly antithetical to the core purpose of the Act:

> [T]hrough the [Hatch-Waxman] Amendments, "Congress sought to get generic drugs into the hands of patients at reasonable prices — fast." We disagree with Andrx that "its conduct was not only permitted under but clearly contemplated by the Hatch-Waxman" Amendments. Although it is true that the first to file an ANDA is permitted to delay marketing as long as it likes, the statutory scheme does not envision the first applicant's agreeing with the patent holder of the pioneer drug to delay [entry].

Andrx Pharm., 256 F.3d at 809 (citations omitted); *see also Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1067 (D.C. Cir. 1998) (collusion between brand and generic

manufacturers is "at odds with Congress's apparent purposes, in enacting [the Act], of rewarding innovation and bringing generic drugs to market quickly").[11]

This Court has repeatedly emphasized the policy in favor of judicial examination of patent validity as a means of protecting consumers from unwarranted patent-based monopolies. The Hatch-Waxman Act specifically incentivized patent challenges in this sector of the economy where unwarranted monopolies cause grievous consumer harm. The Second Circuit standard allows patentees to countermand the statutory incentive and buy a shield from judicial examination of the legitimacy of their patents.

Conflict With the Court's Antitrust Cases. The Second Circuit standard also violates this Court's fundamental antitrust principles. For more than a century, this Court has held that it is anticompetitive for a firm to pay a competitor to exit or stay out of the market. *See, e.g., United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 293-94 (6th Cir. 1898), *aff'd*, 175 U.S. 211 (1899); *United States v. Topco Assocs., Inc.*, 405 U.S.

---

11. *See also Terazosin*, 352 F. Supp. 2d at 1298 (sham litigation standard "would give the patent holder rights beyond those granted by the Patent Act, and beyond the structure contained in the Hatch-Waxman Act"); C. Scott Hemphill, *Paying For Delay: Pharmaceutical Patent Settlement As A Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1614-16 (2006) ("The Hatch-Waxman Act's calibration between innovation and competition is disrupted if firms are free to engage in self-help. The resulting disruption is difficult to square with the policies that animate the Hatch-Waxman Act. . . .").

596, 608-09 (1972). Paying competitors not to enter is anticompetitive even when potential entry barriers — whether economic or legal — make it uncertain whether the competitor's attempt to enter would have succeeded. *See, e.g., Palmer*, 498 U.S. at 48-49; *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (en banc); XII Hovenkamp, ANTITRUST LAW ¶ 2030b at 213 (2d ed. 2005). "Such agreements are anticompetitive regardless of whether the parties split a market within which both [currently] do business. . . ." *Palmer*, 498 U.S. at 49.

A patent is a potential entry barrier, and this Court has never afforded patentees antitrust immunity for paying competitors not to try to overcome them. The Second Circuit derived its patent fraud/sham litigation standard from this Court's decisions in *Walker Process Equip., Inc. v. Ford Mach. & Chem. Corp.*, 382 U.S. 172, 175-77 (1965), and *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993). But those cases provide the standard for imposing antitrust liability on a monopolist's constitutionally protected conduct in petitioning the government to restrain competition by granting and enforcing a patent. An exclusion payment settlement withdraws such a petition from the government and instead restrains competition by private treaty. This private conduct enjoys no immunity warranting such a lenient antitrust standard. *See, e.g., Federal Trade Comm'n v. Superior Court Trial Lawyers Ass'n*, 493 U.S. 411, 424-25 (1990) (immunity applies only when "the alleged restraint of trade [is] the intended consequence of public action"). A patentee that makes exclusion payments helps itself to guaranteed exclusion that government procedures simply do not provide:

> What the pharmaceutical patentees who agree to exclusion payments seek is something more [than the legitimate exclusionary power of the patent] — a guaranteed insulation from competition, without the risk that the patent is held invalid. IP policy does not offer such a guarantee, and does not immunize from antitrust scrutiny those who seek it by entering into agreements that exclude potential competitors.

Hovenkamp, *Anticompetitive Settlements*, 87 MINN. L. REV. at 1761-62.

Moreover, *Walker Process* and *PRE* provide the standards for imposing antitrust liability on a defendant's *unilateral* conduct in obtaining and enforcing a patent. But making and accepting an exclusion payment is collusive, not unilateral; it combines the economic interests of two competitors whose unilateral interests were previously to affirm, and to deny, respectively, the patent's validity. This Court's precedents apply significantly more stringent antitrust standards to collusive than to unilateral conduct. *See, e.g., Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984); *accord United States v. Singer Mfg. Co.*, 374 U.S. 174, 199-200 (1963) (White, J., concurring) (settlement of patent interference was unlawful because it was not "purely unilateral action" but instead reflected "collusion among applicants to prevent prior art from coming to or being drawn to the [PTO's] attention"). The Second Circuit standard would impose antitrust liability on exclusion payment agreements only when the patentee's request that the government restrain

competition would itself be unlawful under Section 2 of the Sherman Act; the standard accords no independent antitrust significance to a patentee's payment to a competitor to forgo having a court decide whether the patent meets the statutory requirements and whether restraining competition is in the public interest.

III. The Court Should Grant Review Because This Case Is the Right Vehicle to Resolve This Recurring Issue of Enormous Public Importance.

This case is the right vehicle for the Court to resolve the circuit split and require compliance with the Court's antitrust and patent precedents. The Court has previously denied certiorari in a number of exclusion payment cases. This case, however, does not suffer from any of the procedural impediments that may have counseled against using those prior cases to resolve these issues whose "'enormous importance' . . . is beyond dispute." Pet. App. 8a.

In both *Tamoxifen* and the Federal Circuit's decision in *Ciprofloxacin*, the petitioners were indirect purchasers who could not recover damages under federal antitrust law, *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), and whose federal claims for injunctive relief had been rendered moot by the expiration of the patents. Brief for the United States as Amicus Curiae, *Joblove v. Barr Labs., Inc.*, No. 06-830 at 17 (S. Ct. May 2007) (advising Court that petitioners' claims were moot); Brief for Bayer, *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, No. 08-1194 at 18 (S. Ct. May 22, 2009) (same). Petitioners here have live federal antitrust claims for damages.

When the Eleventh Circuit's adoption of the patent relitigation standard first caused the circuit split, the United States recommended against review because of, *inter alia*, a threshold factual dispute in that case as to whether the brand had made any payment to the generic. Brief for the United States as Amicus Curiae, *Federal Trade Comm'n v. Schering-Plough Corp.*, No. 05-273 (S. Ct. May 2006).[12] The brand had agreed to pay royalties to the generic ostensibly for use of some of its technology, and the threshold issue was whether this was an above-market-price agreement that was in reality a disguised exclusion payment, or was instead a bona fide royalty agreement. *Id.* at 12-13.

A comprehensive analysis of all known exclusion payment settlements has concluded that all recent agreements, unlike the one at issue here, have taken the form of a disguised payment from the brand to the generic, similar to the one used in *Schering*. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 649 (2009). Thus, every antitrust case premised on those exclusion payments will present a threshold factual question of whether the brand made a payment to the generic. *See, e.g., In re Androgel Antitrust Litig.*, 687 F. Supp. 2d 1371, 1375 (N.D. Ga. 2010) (alleging disguised payment

12. The United States also disagreed with the FTC on the merits of that case. U.S. Br., *Schering-Plough Corp.*, No. 05-273 at 11-12. In contrast, the United States has consistently argued that the Second Circuit standard is "incorrect" and "insufficiently stringent." U.S. Br., *Joblove*, No. 06-830 at 1, 8; *see also* U.S. Br. at 6 (quoting *Tamoxifen*, 466 F.3d at 224 (Pooler, J., dissenting)).

in form of above-market-price contract); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 702 F. Supp. 2d. 514, 522-23 (E.D. Pa. 2010) (same); *K-Dur*, 2009 WL 508869 at *7 (same).

The problem of exclusion payments and the proper liability standard is not abating — manufacturers used at least forty exclusion payment agreements to restrict generic entry in the last two years. This case provides the Court with its best opportunity to resolve the circuit split over the appropriate legal standard without having to address it in the context of a factual dispute as to whether a complex commercial arrangement between the brand and generic is actually a disguised exclusion payment. Hemphill, *An Aggregate Approach to Antitrust*, 109 COLUM. L. REV. at 663.

The question of the proper standard for determining whether an exclusion payment is anticompetitive has been percolating in the courts, and thoroughly debated in academia, for over a decade. The three potential standards that have emerged are reflected in the three-way circuit split. This case presents the best opportunity for the Court to resolve the circuit split, require compliance with the Court's patent and antitrust precedents, and restore the Hatch-Waxman Act balance between extending pharmaceutical patent terms and preserving judicial review of those patents to ensure that the resulting monopolies are warranted.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

BRUCE E. GERSTEIN
GARWIN GERSTEIN &
FISHER LLP
1501 Broadway,
Suite 1416
New York, NY 10036
(212) 398-0055

DAVID F. SORENSEN
BERGER & MONTAGUE, P.C.
1622 Locust Street
Philadelphia, PA 19103
(215) 875-3000

Counsel for Petitioner Louisiana Wholesale Drug Co., Inc.

STEVE D. SHADOWEN
Counsel of Record
MONICA L. REBUCK
HANGLEY ARONCHICK SEGAL
& PUDLIN
30 N. Third Street,
Suite 700
Harrisburg, PA 17101
(717) 364-1030
sshadowen@hangley.com

Counsel for Petitioners CVS Pharmacy, Inc. and Rite Aid Corporation

TIMOTHY D. BATTIN
STRAUS & BOIES, LLP
4041 University Drive
Fairfax, VA 22030
(703) 764-8700

Counsel for Petitioner Arthur's Drug Store, Inc.

APPENDIX A — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT DATED SEPTEMBER 7, 2010

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

05-2851-cv(L)
05-2852-cv(CON)
05-2863-cv(CON)*

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Daniel Patrick Moynihan United States Courthouse, 500 Pearl Street, in the City of New York, on the 7th day of September, two thousand ten.

- - - - - - - - - - - - - - - - - - -

ARKANSAS CARPENTERS HEALTH AND WELFARE FUND, MARIA LOCURTO, PAPER, ALLIED-INDUS, UNITED FOOD AND COMMERCIAL WORKERS UNION-EMPLOYER, LOUISIANA WHOLESALE DRUG CO., INC., CVS PHARMACY, INC., RITE AID CORPORATION, ARTHUR'S DRUG STORE, INC.,

Plaintiffs-Appellants,

*The appeal docketed under 05-2863-cv has been transferred to the United States Court of Appeals for the Federal Circuit. *See* Nov. 7, 2007 Order.

Appendix A

SOL LUBIN, ANN STUART,
LINDA K. MCINTYRE,

Plaintiffs,

- v.-

BAYER AG, BAYER CORP., formerly doing business as MILES INC., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., WATSON PHARMACEUTICALS, INC., BARR LABORATORIES INC.,

Defendants-Appellees.

ORDER

Following disposition of this appeal on April 29, 2010, Plaintiffs-Appellants Louisiana Wholesale Drug Co., Inc.; Arthur's Drug Store, Inc.; CVS Pharmacy, Inc.; and Rite Aid Corporation filed a petition for rehearing *in banc*. An active judge requested a poll on whether to rehear the case *in banc*. A poll having been conducted and there being no majority favoring *in banc* review, rehearing *in banc* is hereby **DENIED**.

Judge Pooler dissents in an opinion.

FOR THE COURT:
CATHERINE O'HAGAN WOLFE, CLERK

Appendix A

ROSEMARY S. POOLER, Circuit Judge, dissenting:[1]

In 1991, Barr Labs sought to market a generic version of ciprofloxacin hydrochloride ("Cipro"). Bayer, which holds the Cipro patent, sued Barr for infringement, lost its motion for summary judgment, and subsequently settled with Barr on the eve of trial. Under the terms of the settlement agreement, Bayer paid Barr nearly $400 million and in exchange Barr agreed not to market a generic version of Cipro during the life of the patent.

The Bayer-Barr settlement agreement was unusual in a number of respects. Most obviously, under the terms of the settlement the *patent holder* agreed to pay the *alleged infringer* to settle the suit in exchange for the alleged infringer's agreement to stay out of the marketplace during the life of the patent. In the industry parlance, this is called a "reverse exclusion payment," or, more evocatively, a "pay-for-delay" settlement.[2]

This type of settlement, once unheard of, has become increasingly common. This Court has played a

---

1. Senior Circuit Judges Jon O. Newman and Barrington D. Parker, members of the original panel, are not authorized to participate in the *en banc* poll, but the panel opinion endorses the views expressed in this opinion.

2. *See generally* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553 (2006).

significant role in encouraging this unfortunate practice. In *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006), a panel of this Court, over my dissent, held that exclusion payment settlements are lawful unless the branded firm's patent is "shown to have been procured by fraud, or a suit for its enforcement is objectively baseless ..." *Id.* at 213. What followed was a dramatic surge in the practice of pharmaceutical patent holders paying potential competitors to concede the validity of their patents. In the five years before *Tamoxifen* was decided, there were no settlements involving exclusion payments,[3] and even pharmaceutical industry representatives appear to have conceded the illegality of the practice, testifying before Congress that proposed amendments to the Hatch Waxman Act explicitly prohibiting exclusion payment settlements were unnecessary because such settlements "would have been violations of the antitrust laws and/or the patent laws whether the Hatch-Waxman Act existed or not."[4] In the four years since *Tamoxifen*, by contrast, the Federal Trade Commission has identified fifty-three pharmaceutical patent settlements involving exclusion

---

3. *See* Jon Leibowitz, Commissioner, Federal Trade Commission, Prepared Statement to the Committee on the Judiciary of the United States Senate: *Anticompetitive Patent Settlements in the Pharmaceutical Industry*, at 13 (Jan. 17, 2007), available at http://www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.pdf.

4. *See Hearing No. 107-1081 Before S. Comm. On Commerce, Science, and Transportation*, 107th Cong. (Apr. 23, 2002), at 71 (statement of Greg Glover, Pharmaceutical Research and Manufacturers of America).

payments.[5] The Commission estimates that such settlements cost consumers approximately $3.5 billion per year.[6] Further, such settlements serve no obvious redeeming social purpose. Put simply, what the patent holder purchases by means of an exclusion payment settlement is the continuation of a patent the patent holder must have thought had some significant probability of being declared invalid.[7]

Of course, all of this would not be this Court's concern if the Hatch-Waxman Act explicitly permitted exclusion payment settlements. However, the Act is silent on the legality of such settlements, and the Act's sponsors have openly criticized the practice.[8] Further,

---

5. *See* Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions: An FTC Staff Study*, at 4 (Jan. 2010), available at www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

6. *Id.* at 8; *see also* Br. of the United States, available at http://www.justice.gov/atr/cases/f259300/259325.htm, at 4 (relying on FTC Staff Study). *Cf.* C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 650 (2009) (estimating the exclusion payments have already cost consumers over $12 billion).

7. Nor, it should be noted, are exclusion payments a patent holder's only means of hedging against this probability. Instead, the probability of invalidation could be reflected in a settlement by means of which the patent holder agrees to some reduction in the unexpired term of the patent.

8. *See* 148 Cong. Rec. S7566 (July 20, 2002) (remarks of Sen. Hatch); *Protecting Consumer Access to Generic Drugs Act of 2007, Hearing No. 110-39 Before H. Comm. on Energy and Commerce*, 110th Cong. At 7 (May 2, 2007) (statement of Rep. Waxman).

exclusion payment settlements seem plainly inconsistent with the stated purpose of the Hatch Waxman Act, which is to encourage patent challenges as a way of increasing consumer access to low-cost drugs.[9]

More significantly, the Hatch Waxman Act does nothing to change the general rule that market-sharing agreements violate the antitrust laws. *See Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49 (1990) (per curiam); *United States v. Sealy, Inc.*, 388 U.S. 350, 357-58 (1967). This is just as true when one of the parties to a market-sharing agreement happens to hold a patent. *See Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49 (1990); *United States v. Sealy, Inc.*, 388 U.S. 350, 357-58 (1967). Thus, even though we are required to presume that Bayer's patent is valid, 35 U.S.C. § 282, as the United States points out in its *amicus* brief,

> [t]he presumption of patent validity is simply a procedural device that assigns burdens in litigation challenging the validity of an issued patent. There is no basis for treating that presumption as virtually conclusive and allowing it to serve as a substantive basis to limit the application of the Sherman Act.

Br. of United States, at 6-7 (internal citations omitted).

---

9. H.R. Rep. No. 98-857(I), at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647-48.

It should not be surprising, therefore, that our *Tamoxifen* decision has inspired vigorous criticism from a variety of sources. The United States has described our *Tamoxifen* rule as "incorrect,"[10] and has supported the plaintiffs' petition for *en banc* rehearing in this case.[11] Also supporting the petition for rehearing are the majority of State Attorneys General,[12] the Federal Trade Commission,[13] the American Medical Association,[14] and an impressive array of consumer groups and academic commentators.[15] As *amici* point out, although "commentators are divided on the treatment to be accorded [exclusion payment] settlements ... none take the position adopted by [] *Tamoxifen*."[16]

---

10. Br. of the United States, *Joblove v. Barr Labs., Inc.*, S. Ct. No. 06-830, available at http://www.justice.gov/osg/briefs/2006/2pet/6invit/2006-0830.pet.ami.inv.html, at 1 (2007).

11. *See* Br. of the United States, *supra* note 5.

12. *See* Br. of 34 State Attorneys General, available at http://www.prescriptionaccess.org/docs/Cipro_2010_May_AG_Amicus.pdf.

13. *See* Br. of FTC, available at http://www.ftc.gov/os/2010/05/051202amicuscarpentershealth.pdf.

14. *See* Br. of AARP & AMA, available at http://www.fdalawblog.net/files/cipro—aarpama.pdf.

15. *See generally* http://blog.prescriptionaccess.org/?cat=422 (collecting links to *amicus* briefs in this case).

16. Br. of 86 Law, Economics, Pub. Pol'y, & Bus. Professors, at 6-7, available at http://www.law.stanford.edu/news/details/3793/Profs%20File%20Amici%20Curiae%20Seeking%20En%20Banc%20Rehearing%20of%20Second%20Circuit%20Pharma%20Reverse%20Payment%20Antitrust%20Decision%20/.

In the light of all this, I think that our *Tamoxifen* decision unambiguously deserves reexamination. The *Tamoxifen* majority recognized the "troubling dynamic" of permitting exclusion payments that "inevitably protect patent monopolies that are, perhaps, undeserved." 466 F.3d at 211. Subsequent experience has shown that the majority was right to be "troubled." Although the "enormous importance" of the issues that this case raises is beyond dispute, Fed. R. App. P. 35(a)(2), a majority of this Court has voted against *en banc* rehearing. I respectfully dissent from that decision. It will be up to the Supreme Court or Congress to resolve the conflict among the Courts of Appeals. *Compare In re Ciprofloxacin Antitrust Litig.*, 544 F.3d 1323, 1333 (Fed. Cir. 2008) (exclusion payments legal), and *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005) (same) *with In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003) (exclusion payments *per se* illegal).

APPENDIX B — DECISION OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT DECIDED APRIL 29, 2010 CORRECTED JUNE 17, 2010

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

Docket Nos. 05-2851-cv(L), 05-2852-cv(CON)

August Term, 2008
Argued: April 28, 2009
Decided April 29, 2010
Corrected June 17, 2010

ARKANSAS CARPENTERS HEALTH AND WELFARE FUND, MARIA LOCURTO, PAPER, ALLIED-INDUS, UNITED FOOD AND COMMERCIAL WORKERS UNION-EMPLOYER, LOUISIANA WHOLESALE DRUG CO., INC., CVS PHARMACY, INC., RITE AID CORPORATION, ARTHUR'S DRUG STORE, INC.,

Plaintiffs-Appellants,

v.

BAYER AG, BAYER CORP., formerly doing business as Miles Inc., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., WATSON PHARMACEUTICALS, INC., BARR LABORATORIES INC.,

Defendants-Appellees.

Appendix B

Before: NEWMAN, POOLER, PARKER, *Circuit Judges.*

Plaintiffs appeal from a judgment of the United States District Court for the Eastern District of New York (Trager, *J.*) granting summary judgment for defendants, manufacturers of the antibiotic ciprofloxacin hydrochloride ("Cipro") or generic bioequivalents of Cipro. Plaintiffs argue that defendants violated Section 1 of the Sherman Act when they settled their dispute concerning the validity of Bayer's Cipro patent by agreeing to a reverse exclusionary payment settlement. Bayer agreed to pay the generic challengers, and in exchange the generic firms conceded the validity of the Cipro patent.

After the district court entered judgment below, a panel of this Court held that reverse payment settlements of patent lawsuits do not violate antitrust laws. *See Joblove v. Barr Labs., Inc., (In re Tamoxifen Citrate Antitrust Litig.)*, 466 F.3d 187, 208-12 (2d Cir. 2005). Because *Tamoxifen* is dispositive of plaintiffs' claims, we AFFIRM. However, because of the "exceptional importance" of the antitrust implications of reverse exclusionary payment settlements of patent infringement suits, we invite plaintiffs-appellants to petition for rehearing in banc. *See* Fed. R. App. P. 35(a)(2).

STEVE D. SHADOWEN, (Monica L. Rebuck, *on the brief*), Hangley Aronchick Segal & Pudlin, Harrisburg, PA (Bruce E. Gerstein, Barry S.

Taus, and Jan Bartelli, Garwin, Gerstein, & Fisher LLP, New York, NY, *on the brief*), for *Plaintiffs-Appellants.*

PAUL E. SLATER, Sperling & Slater, P.C., of counsel to Amicus Curiae American Antitrust Institute, Chicago, IL, in support of *Plaintiffs-Appellants.*

STACY J. CANAN, (Bruce Vignery, *on the brief*), AARP Foundation Litigation, (Michael Schuster, AARP, *on the brief*), Washington, D.C., as Amici Curiae for *Plaintiffs-Appellants.*

DON L. BELL, II, National Association of Chain Drug Stores, Inc., Alexandria, VA, as Amicus Curiae for *Plaintiffs-Appellants.*

FRED H. BARTLIT, Jr., (Peter B. Bensinger, Jr., Michael J. Valaik, and Paul J. Skiermont, *on the brief*), Bartlit Beck Herman Palenchar & Scott LLP, Chicago, IL, (Philipp A. Proger, Kevin D. McDonald, and Lawrence D. Rosenberg, Jones Day, Washington, DC), for *Defendants-Appellees Bayer AG and Bayer Corporation.*

KAREN N. WALKER, (Edwin John U, Bridget K. O'Connor, and Gregory L. Skidmore, *on the brief*), Kirkland & Ellis LLP, Washington, DC, (David E. Everson, Heather S. Woodson, and Victoria L. Smith, Stinson Morrison Hecker LLP,

Appendix B

Kansas City, MO, *on the brief*), for *Defendants-Appellees Barr Laboratories, Inc., Hoechst Marion Roussel, Inc., The Rugby Group, Inc., and Watson Pharmaceuticals, Inc.*

CHRISTINE A. VARNEY, Assistant Attorney General, (Philip J. Weiser, Deputy Assistant Attorney General, and Catherine G. O'Sullivan and David Seidman, Attorneys), U.S. Department of Justice, Washington, D.C., for *the United States.*

PER CURIAM:

Plaintiffs appeal from a judgment of the United States District Court for the Eastern District of New York (Trager, *J.*) granting summary judgment for defendants. Defendants Bayer AG and its subsidiary Bayer Corporation (collectively "Bayer") own the patent for the active ingredient in the antibiotic ciprofloxacin hydrochloride ("Cipro"). Defendants Barr Laboratories, Inc. ("Barr"), Hoechst Marion Roussel, Inc. ("HMR"), and Watson Pharmaceuticals, Inc. ("Watson") were potential generic manufacturers of Cipro. Plaintiffs are direct purchasers of Cipro, who allege that defendants violated federal antitrust law when they settled a patent infringement lawsuit by entering into collusive agreements that blocked the entry of low-cost generic versions of Cipro into the prescription drug market.

Appendix B

BACKGROUND

Hatch-Waxman Settlement Agreements

Bayer is the owner of the patent relating to the active ingredient in Cipro, which has been described as the most prescribed antibiotic in the world. The Cipro patent, U.S. Patent No. 4,670,444, was issued on June 2, 1987 and was scheduled to expire on December 9, 2003.[1]

In 1991, Barr sought to market a generic version of Cipro pursuant to the expedited FDA approval process established by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585. Under the Hatch-Waxman Act, a pharmaceutical company can seek approval to market generic versions of an approved branded drug without having to re-establish the drug's safety and effectiveness by filing an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(j)(2)(A), (8)(B). Where, as here, a generic manufacturer seeks to enter the market before the expiration of the branded firm's patent, it must file a pre-expiration challenge ("paragraph IV" or "ANDA-IV" certification). 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The ANDA-IV certification requires the generic firm to demonstrate the bioequivalence of its proposed version of the drug, *see*

1. Bayer obtained an additional six-month period of pediatric exclusivity from the Food and Drug Administration (FDA) until June 9, 2004. *See* 21 U.S.C. § 355a(b)(1)(B)(i)(II).

21 C.F.R. § 314.94(a)(9), and to state the basis for its claim of invalidity or noninfringement of the branded firm's patent, *see* 21 U.S.C. § 355(j)(2)(B)(iv)(II).

An ANDA-IV certification itself constitutes an act of infringement, triggering the branded manufacturer's right to sue. 35 U.S.C. § 271(e)(2)(A). Indeed, the branded manufacturer *must* sue within 45 days of receiving notice of the ANDA-IV in order to stay the generic firm's entry into the market. 21 U.S.C. § 355(j)(5)(B)(iii).[2] Thus, the Hatch-Waxman Act redistributes the relative risks between the patent holder and the generic manufacturer, allowing generic manufacturers to challenge the validity of the patent without incurring the costs of market entry or the risks of damages from infringement. *See Ark. Carpenters Health & Welfare Fund v. Bayer AG (In re Ciprofloxacin Hydrochloride Antitrust Litig.)*, 544 F.3d 1323, 1338 (Fed. Cir. 2008).

The first generic firm to file an ANDA-IV is rewarded with a 180-day exclusive right to market its

2. Although this statutory stay is typically called the "thirty-month stay," in fact the stay can last for over four years. *Compare* 21 U.S.C. § 355(j)(5)(B)(iii) (default maximum duration of stay is thirty months provided notice of ANDA IV is received more than five years after ANDA approval) *with* § 355(j)(5)(F)(ii) (result of earlier-filed ANDA IV is that stay is lengthened, ending five years plus thirty months after FDA approval of the branded drug).

generic version of the drug. 21 U.S.C. § 355(j)(5)(B)(iv).[3] However, *only* the first-filed ANDA-IV is eligible for the 180-day exclusivity period: even if the first filer loses, withdraws, or settles its challenge, subsequent filers do not become eligible for the exclusivity period.[4]

The Bayer-Barr Lawsuit

Barr filed an ANDA-IV challenging Bayer's Cipro patent in October 1991.[5] Bayer sued Barr for patent infringement in the Southern District of New York

3. This 180-day exclusivity period became law without discussion in the relevant House Report and without debate. *See* H.R. Rep. No. 98-857, p. 1, at 28 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2661. Moreover, it was apparently not contemplated at the time of passage that the regulatory scheme would facilitate collusion between branded and generic firms. *See* e.g., S. Rep. No. 107-167, at 4 (2002) ("Agreeing with smaller rivals to delay or limit competition is an abuse of the Hatch-Waxman law . . . .").

4. In *Joblove v. Barr Labs. Inc, (In re Tamoxifen Citrate Antitrust Litig.)*, 466 F.3d 187 (2d Cir. 2005) ("*Tamoxifen*"), the panel majority suggested otherwise, repeating the district court's claim that the exclusivity period cedes to the first ANDA filer to successfully defend. *Compare Tamoxifen*, 466 F.3d at 214, *with In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 134 (E.D.N.Y. 2003). As we discuss in Section 5, *infra*, this aspect of our *Tamoxifen* decision was erroneous. *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement As a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1583-86 (2006).

5. Barr claimed that the patent was invalid on the following grounds: (1) obviousness; (2) obviousness type double counting; and (3) inequitable conduct.

within 45 days of its receipt of notice of Barr's filing, triggering the Hatch-Waxman statutory stay.[6] Barr subsequently entered into an agreement with other defendants herein, also potential generic manufacturers of Cipro, to share the costs and benefits of the patent litigation.

In June 1996, the district court denied the parties' cross-motions for summary judgment. In January 1997 — approximately two weeks prior to the scheduled trial — Bayer and Barr entered into a "reverse exclusionary payment" (or "pay-for-delay") settlement: that is, the patent holder (Bayer) agreed to pay the alleged infringer to settle the lawsuit, and in exchange, the alleged infringer agreed not to enter the market.[7] Under the terms of the settlement agreement, Bayer agreed to (1) pay $49.1 million immediately; (2) make quarterly payments of between $12.5 and $17.125 million for the duration of the patent except for the last six months prior to the patent's expiration;[8] and (3) provide the

6. The parties subsequently agreed to extend the stay until after the entry of final judgment.

7. To be more precise, the parties executed separate settlement agreements between: (1) Bayer and Barr, and (2) Bayer and HMR/Rugby, which was subsequently acquired by Watson. Bayer, Barr, and HMR also executed a supply agreement.

8. As an alternative to quarterly payments, the settlement gave Bayer the right to either provide Barr with a license to sell Bayer-manufactured Cipro at a royalty rate of 70% of Bayer's average selling price for brand-name Cipro. Bayer elected to make quarterly payments instead. Settlement payments ultimately totaled $398.1 million.

generic manufacturers a guaranteed license to sell brand-name Cipro at a reduced rate for six months prior to the patent's expiration. In exchange, Barr conceded the patent's validity and agreed not to market a generic version of Cipro prior to the patent's expiration.[9]

Plaintiffs' Antitrust Lawsuit

In 2000, direct and indirect purchasers of Cipro filed over thirty antitrust lawsuits against Bayer under federal and state law. These cases were consolidated by the Multi-District Litigation Panel in the Eastern District of New York. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 166 F. Supp. 2d 740, 745 (E.D.N.Y. 2001) ("*Cipro I*"). Plaintiffs allege that defendants' settlement exceeded the scope of Bayer's patent rights because Bayer effectively paid its potential competitors hundreds of millions of dollars not to challenge its patent. Plaintiffs also allege that the agreements were unlawful because Barr was permitted to reclaim the 180-day market exclusivity period if a subsequent challenger was successful in having the

9. Barr reserved its right to reinstate its ANDA-IV if Bayer's patent were later held to be invalid. Four generic manufacturers – Ranbaxy, Schein, Mylan, and Carlsbad – subsequently challenged the Cipro patent. Ranbaxy's challenge was dismissed as moot in October 1999. Mylan's and Schein's consolidated challenges were dismissed at summary judgment and this dismissal was affirmed on appeal. *Bayer AG v. Schein Pharm., Inc.*, 129 F. Supp. 2d 705 (D.N.J. 2001), *aff'd*, 301 F.3d 1306 (Fed. Cir. 2002). Carlsbad's challenge was rejected after a nine-day bench trial. *Bayer AG v. Carlsbad Tech., Inc.*, No. Civ. 01-867-B (S.D. Cal. Aug. 26, 2002).

patent invalidated, and because the generic manufacturers agreed not to file any ANDA-IV certifications for products that relate to Cipro. But for the challenged agreements, plaintiffs assert that (1) Barr would have entered the market pending resolution of the patent litigation; (2) Barr would have prevailed in the litigation and entered the market; or (3) Bayer would have granted Barr a license to market a generic version of Cipro to avoid a trial on the patent's validity. On cross-motions for summary judgment, the district court granted summary judgment for the defendants. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 548 (E.D.N.Y. 2005) ("*Cipro III*"). The court stated:

> The ultimate question – and this is the crux of the matter – is not whether Bayer and Barr had the power to adversely affect competition for ciprofloxacin as a whole, but whether any adverse effects on competition stemming from the Agreements were outside the exclusionary zone of the '444 Patent. It goes without saying that patents have adverse effects on competition. However, any adverse effects within the scope of a patent cannot be redressed by antitrust law.

Id. at 523-24 (citations omitted). In eschewing a "*post hoc* determination of the potential validity of the underlying patent," the court reasoned that "such an approach would undermine the presumption of validity of patents in all cases, as it could not logically be limited

to drug patents, and would work a revolution in patent law." *Id.* at 529.

The district court also found that the agreements did not allow Barr to manipulate the exclusivity period to obstruct subsequent challengers of the patent. *Id.* at 540-41; *see also Cipro II*, 261 F. Supp. 2d at 243-47. The court summarized as follows:

> [I]n the absence of any evidence that the Agreements created a bottleneck on challenges to the '444 Patent, or that they otherwise restrained competition beyond the scope of the claims of the '444 Patent, the Agreements have not had any anti-competitive effects on the market for ciprofloxacin beyond that which are permitted under the '444 Patent. The fact that Bayer paid what in absolute numbers is a handsome sum to Barr to settle its lawsuit does not necessarily reflect a lack of confidence in the '444 Patent, but rather the economic realities of what was at risk. There is simply no precedent for plaintiffs' argument that the parties to a settlement are required to preserve the public's interest in lower prices. Such a rule would only result in parties being less likely to reach settlements, aside from undermining well-settled principles of patent law. Finally, to even attempt to quantify the public's interest in a patent settlement between private parties would require

> devaluing patents across the board, a result that would contravene the presumption of validity afforded by Congress and impact the very way patent licenses are handled in countless daily transactions.

Cipro III, 363 F. Supp. 2d at 540-41.

Plaintiffs timely appealed. This Court retained jurisdiction over the direct purchaser plaintiffs' appeals, but transferred the indirect purchaser plaintiffs' appeal to the Federal Circuit.[10]

DISCUSSION

We review the district court's grant of summary judgment *de novo*, construing evidence in the manner most favorable to the nonmoving party. *Horvath v. Westport Library Ass'n*, 362 F.3d 147, 151 (2d Cir. 2004)

---

10. The indirect purchaser plaintiffs amended their complaint to add state-law, *Walker Process* antitrust claims, so-called based on the Supreme Court's decision in *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, which recognized an antitrust claim when patents are obtained by fraud. 382 U.S. 172, 177 (1965). Because the *Walker Process* claims are preempted by patent law, *see Cipro III*, 363 F. Supp. 2d at 543-44, we transferred the indirect purchaser plaintiffs' appeal to the Federal Circuit, while retaining jurisdiction over the direct purchaser plaintiffs' appeals. The Federal Circuit ultimately affirmed the district court on the indirect purchaser plaintiffs' claims, agreeing with the district court's conclusion that the settlement did not restrain competition beyond the exclusionary zone of the Cipro patent. 544 F.3d 1323, 1333 (Fed. Cir. 2008).

(citation omitted). Summary judgment is appropriate only where "there is no genuine issue as to any material fact and . . . the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

1. Section 1 of the Sherman Act

The Sherman Act provides that "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal." 15 U.S.C. § 1. Although by its terms, the Act prohibits "every" restraint of trade, the Supreme Court "has long recognized that Congress intended to outlaw only unreasonable restraints." *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997). Agreements that have a "predictable and pernicious anticompetitive effect, and . . . limited potential for procompetitive benefit" are deemed per se unlawful. *Id.* Most conduct, however, is subject to so-called "rule of reason" analysis. *See Texaco Inc. v. Dagher*, 547 U.S. 1, 5 (2006).

Rule of reason analysis proceeds in three steps. First, the plaintiff bears the initial burden of showing that the defendant's conduct "had an *actual* adverse effect on competition as a whole in the relevant market." *Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs., Inc.*, 996 F.2d 537, 543 (2d Cir. 1993) (emphasis in original). If plaintiff satisfies this burden, the burden then shifts to defendant to offer evidence that its conduct had pro-competitive effects. *Id.* If defendant is able to offer such proof, the burden shifts back to

plaintiff, who must prove that any legitimate competitive effects could have been achieved through less restrictive alternatives. *Id.*

2. Reverse Exclusionary Payment Settlements, Antitrust Law, and *Tamoxifen*

Plaintiffs argue that when Bayer paid Barr to withdraw its challenge to the Cipro patent, defendants effectively entered into a market-sharing agreement in restraint of trade. Patent settlements, like all private contracts, are subject to antitrust scrutiny. *Cf. Standard Oil Co. v. United States*, 283 U.S. 163, 169 (1931) ("The limited monopolies granted to patent owners do not exempt them from the prohibitions of the Sherman Act . . . ."); *see also B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1426-27 (Fed. Cir. 1997) (the Sherman Act prevents patentees from obtaining a greater monopoly than was inherent in the relevant patent grant). Thus, like ordinary contracts, patent settlements cannot take the form of "market-sharing agreements." *See Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49 (1990) (per curiam) (market-sharing agreement is unlawful on its face); *United States v. Sealy, Inc.*, 388 U.S. 350, 357-58 (1967) (same); *see also* 12 Herbert Hovenkamp, *Antitrust Law* ¶ 2030b, at 213 (2d ed. 2005) ("[T]he law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition").

The question, therefore, is whether patent settlements in which the generic firm agrees to delay

entry into the market in exchange for payment fall within the scope of the patent holder's property rights, or whether such settlements are properly characterized as illegal market-sharing agreements. Authorities are divided on this question. The Federal Trade Commission ("FTC"), the U.S. antitrust enforcement agency charged with supervising the pharmaceutical industry, has long insisted that reverse exclusionary payment settlements violate antitrust law and has challenged numerous agreements as unreasonable restraints of trade.[11] Although it initially took a different view, the United States has since maintained that reverse exclusionary payment settlements may violate antitrust laws. *See* Brief for the United States as Amicus at 12, *Joblove v. Barr Labs., Inc.*, No. 06-830, 2007 WL 1511527 (U.S. May 23, 2007). Many academic commentators share the United States's view.[12]

11. *E.g. Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. (2007) (statement of Jon Leibowitz, FTC Commissioner), available at http://www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.pdf (criticizing the "extremely lenient view" taken by some toward reverse exclusionary agreements and alleging that reverse exclusionary agreements result in massive wealth transfers from consumers to pioneer drug producers); *see also Concurring Statement of Commissioner Jon Leibowitz, FTC v. Watson Pharmaceuticals et. al.* (Feb. 2, 2009), available at http://ftc.gov/speeches/leibowitz/090202watsonpharm.pdf.

12. *See, e.g.*, C. Scott Hemphill, *Paying for Delay*, 81 N.Y.U. L. Rev. at 1561-62 (2006) (arguing that a settlement should be accorded a presumption of illegality if the settlement both

(Cont'd)

Most courts, by contrast, including this Court, *Joblove v. Barr Labs. Inc., (In re Tamoxifen Citrate Antitrust Litig.)*, 466 F.3d 187, 216 (2d Cir. 2005) ("*Tamoxifen*"), have held that the right to enter into reverse exclusionary payment agreements fall within the terms of the exclusionary grant conferred by the branded manufacturer's patent. *See In re Ciprofloxacin Antitrust Litig.*, 544 F.3d at 1333; *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005). *But see La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (In re Cardizem CD Antitrust Litig.)*, 332 F.3d 896, 908 (6th Cir. 2003) (holding such agreements to be per se illegal); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005) (same).

Particularly relevant here is this Court's decision in *Tamoxifen*. The plaintiffs in *Tamoxifen* challenged a reverse exclusionary payment settlement between

---

(Cont'd)
restricts the generic firm's ability to market a competing drug and includes compensation from the innovator to the generic firm); Herbert Hovenkamp, Mark Janis, & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1759-60 (2003) (proposing that a defendant would overcome the presumptive unlawfulness of a reverse payment settlement by "showing both (1) that the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit"). *But see* Alan Devlin, *The Stochastic Relationship Between Patents and Antitrust*, 5 J. Competition L. & Econ. 75, 108 (2009) ("uncritical application of standard principles of competition law to information markets may be myopic.").

Zeneca and Barr that the parties entered into after a district court had declared Zeneca's patent invalid. 466 F.3d at 193. At the 12(b)(6) stage, *Tamoxifen* rejected as speculative plaintiffs' allegation that Barr would have prevailed on appeal but for the settlement agreement. *Id.* at 203-04. Assuming the truth of plaintiffs' allegation that the exclusion payments exceeded the profits Barr would have obtained upon entering the market as a generic competitor, the *Tamoxifen* court determined that the plaintiffs had no antitrust claim because a patent holder is entitled to protect its "lawful monopoly over the manufacture and distribution of the patented product." *Id.* at 205, 208-09.

Notably, *Tamoxifen* expressly adopted aspects of the lower court's summary judgment decision in this case, holding:

> Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.

Id. at 213 (citing *Cipro III*, 363 F. Supp. 2d at 535). The *Tamoxifen* court ruled that the settlement agreement did not exceed the scope of the patent where (1) there was no restriction on marketing non-infringing products; (2) a generic version of the branded drug would necessarily infringe the branded firm's patent; and (3)

the agreement did not bar other generic manufacturers from challenging the patent. *Id.* at 213-15; *cf. Cipro III*, 363 F. Supp. 2d at 540-41; *Cipro II*, 261 F. Supp. 2d at 241-47.

Since *Tamoxifen* rejected antitrust challenges to reverse payments as a matter of law, we are bound to review the *Cipro* court's rulings under the standard adopted in *Tamoxifen*. *See* 466 F.3d at 208-12. We therefore proceed to evaluate plaintiffs' claims under *Tamoxifen*.[13] Plaintiffs do not argue that the patent infringement lawsuit was a sham or that the Cipro patent was procured by fraud. Thus, the only reasonable basis for distinguishing *Tamoxifen* would be if plaintiffs demonstrated that the settlement agreement here, unlike in *Tamoxifen*, exceeded the scope of the Cipro patent. Plaintiffs cannot establish this because a generic version of Cipro would necessarily infringe Bayer's patent. *Tamoxifen* explained that unlike "formulation patents," which cover only specific formulations or delivery methods for a compound, a "compound patent" "by its nature, excludes all generic versions of the drug." 466 F.3d at 214. Bayer's Cipro patent is a compound patent. *Id.* Thus, Barr's agreement to refrain from manufacturing generic Cipro encompasses only conduct that would infringe Bayer's patent rights.

Plaintiffs also claim that the challenged agreements contained ancillary restraints outside the scope of the

---

13. Our jurisdiction over plaintiffs' claims is also established by *Tamoxifen*. *See* 466 F.3d at 199-200.

patent: (1) Barr was permitted under the agreements to manipulate its rights to the 180-day market exclusivity period; and (2) Barr and HMR agreed to refrain from filing future ANDA-IV certifications related to Cipro.[14] *Tamoxifen* recognized that a plaintiff can have antitrust claims where a Hatch-Waxman settlement allows the generic manufacturer to manipulate the 180-day exclusivity period in a manner that bars subsequent challenges to the patent or precludes the generic manufacturer from marketing non-infringing products unrelated to the patent. *See Tamoxifen*, 466 F.3d at 213-19; *see also Cardizem CD*, 332 F.3d at 907-09. In this case, however, plaintiffs have not shown that the settlement agreements allowed manipulation of the exclusivity period or prohibited the marketing of non-infringing products.

Plaintiffs contend that Barr's insistence on its right to reclaim the 180-day exclusivity period caused other generic manufacturers to delay subsequent challenges. Specifically, they maintain that Mylan delayed its challenge because it perceived Barr's continued assertion of a right to the 180-day exclusivity as an obstruction to their entry into the market. This argument is unpersuasive. Although the settlement agreement allows Barr to reinstate its ANDA-IV if a subsequent patent challenge were successful, a

---

14. Plaintiffs argued below that the agreements were unlawful because Barr and HMR conceded the validity of several additional patents related to Cipro. *See Cipro II*, 261 F. Supp. 2d at 254. Plaintiffs do not press this argument on appeal.

reinstated ANDA-IV certification would not have entitled Barr to the 180-day exclusivity period based on the law in effect at the time of settlement.[15] Thus, the district court properly determined that Barr forfeited its challenge to the patent and thus any right to 180-day exclusivity, and that other generic manufacturers were able to subsequently challenge the Cipro patent.

---

15. When Bayer and Barr entered the settlement in January 1997, an ANDA filer's right to 180-day exclusivity was contingent on their "successful defense" of a patent infringement suit. *See* 21 C.F.R. § 314.107(c)(1). Since Barr did not successfully defend the lawsuit by entering a settlement, the court found it had no claim to the exclusivity period. *Cipro II*, 261 F. Supp. 2d at 243, 247. After courts rejected the FDA's "successful defense" requirement, *see, e.g.*, *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998), the FDA permanently removed it. *See* Effective Date and Approval of an Abbreviated New Drug Application, 63 Fed. Reg. 59710, 57911 (Nov. 5, 1998). But this occurred after the agreements in this case were executed. Plaintiffs argue that the questionable validity of the regulation suggests that Barr tried to exploit it in order to keep other manufacturers from the market, but *Tamoxifen* specifically rejected this argument. 466 F.3d at 218-19. Plaintiffs assert that the *Tamoxifen* panel did not consider a district court case that found an earlier FDA exclusivity requirement contrary to the Hatch-Waxman statute. *See Inwood Labs., Inc. v. Young*, 723 F. Supp. 1523 (D.D.C. 1989), *vacated as moot*, 43 F.3d 712 (D.C. Cir. 1989). However, this argument is unavailing because the FDA promulgated the "successful defense" requirement in effect at the time of the agreements here after the *Inwood Labs* decision. *See* Abbreviated New Drug Application Regulations; Patent and Exclusivity Provision, 59 Fed. Reg. 50338 (Oct. 3, 1994). The established law at the time of the agreement precluded Barr from retaining a right to exclusivity.

See Cipro II, 261 F. Supp. 2d at 243;[16] *cf. Tamoxifen*, 466 F.3d at 218-19 (rejecting a claim that Barr manipulated the 180-day exclusivity period based on similar analysis).

Finally, plaintiffs argue that Barr and HMR unlawfully agreed to refrain from filing ANDA-IVs even after the Cipro patent expired. The agreement states that Barr and HMR are "not to . . . file any [ANDA] relating to Cipro with . . . a certification made pursuant to Paragraph IV of the Act." The district court reasonably interpreted the agreement to mean that Barr and HMR would not file any ANDA-IV certifications challenging the validity of the Cipro patent. *See Cipro II*, 261 F. Supp. 2d at 253. This reading was consistent with Barr's concession of validity and with the fact that there could not be an ANDA-IV certification for a non-infringing version of the drug since Bayer had a compound patent.

Plaintiffs contend that *Tamoxifen* is distinguishable because, by relying on the district court's *Cipro III*

16. Plaintiffs contend that the district court erred in *Cipro III* when it admitted that, based on its ruling in *Cipro II*, it need not consider this claim "anew." *See* 363 F. Supp. 2d at 540 (citing *Cipro II*, 261 F. Supp. 2d at 243-47). *Cipro II* considered the claim in the context of plaintiffs' motion for partial summary judgment. When addressing defendants' motion for summary judgment in *Cipro III*, the district court was required to view the evidence in plaintiffs' favor. Because the district court's analysis is consistent with *Tamoxifen*, which was decided at the 12(b)(6) stage, the district court did not err by incorporating its analysis from *Cipro II*.

decision, *Tamoxifen* adopted an erroneous view of the facts of this case *i.e.22*, *Tamoxifen* was based on an erroneous view of the facts of *Cipro*. This argument is not persuasive. *Tamoxifen* relied on *Cipro III* not for its facts, but rather for its legal and policy analysis. The *Tamoxifen* majority urged against addressing the probability that a patent was invalid and deferred to a patent holder's desire to settle patent challenges, concluding that a patent holder could reasonably decide to pay money, even more than a generic manufacturer would make on the market, to guarantee protection of its patent. *See Tamoxifen*, 466 F.3d at 210 ("[A] rule [limiting the amount of exclusion payments] would . . . fail to give sufficient consideration to the patent holder's incentive to settle . . . .").

Plaintiffs and amici also argue that *Tamoxifen* runs afoul of the purpose of the Hatch-Waxman Act. The purpose of the Hatch-Waxman Act, 21 U.S.C. § 355, was "to make available more low cost generic drugs." H.R. Rep. No. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647. The Act sought to accomplish this objective by providing an incentive through the ANDA-IV certification procedure for generic manufacturers to challenge presumptively valid patents, which, if successful, would result in exclusivity for the first successful challenger and the entry of generic drugs into the market. The market entry of generic drugs arising from successful Hatch-Waxman challenges can result in significant savings to consumers. *See* Brief for AARP as Amicus at 8-9 (discussing generic manufacturers' challenges to the Prozac patent and

Paxil patent where generic entry resulted in $2.5 and $2 billion in consumer savings, respectively).[17]

These policy arguments cannot be addressed here. As defendants note, this panel is bound by *Tamoxifen* "absent a change in law by higher authority or by way of an in banc proceeding." *United States v. Snow*, 462 F.3d 55, 65 n.11 (2d Cir. 2006). However, there are several reasons why this case might be appropriate for reexamination by our full Court.

First, the United States has itself urged us to repudiate *Tamoxifen*, arguing that *Tamoxifen* adopted an improper standard that fails to subject reverse exclusionary payment settlements to appropriate antitrust scrutiny. Brief for the United States as Amicus at 6, 14-15;[18] *see also* Brief for the United States as Amicus in *Joblove v. Barr Labs., Inc.*, No. 06-830, 2007 WL 1511527, at *1 (U.S. May 23, 2007) (describing the *Tamoxifen* standard as "incorrect"). In the pending case, the United States argues:

---

17. One study found that generic manufacturers prevailed in 73% of the Hatch-Waxman lawsuits that were tried to verdict. *See* Brief for American Antitrust Institute ("AAI") as Amicus at 3 (citing *Generic Drug Entry Prior to Patent Expiration*, at vii (2002), available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf).

18. The Department of Justice provided a brief at the request of the panel. Though the United States argues that our *Tamoxifen* decision was wrongly decided, it "takes no position on the ultimate merits of this appeal." Brief for the United States as Amicus at 9.

Appendix B

> This Court's *Tamoxifen* standard inappropriately permits patent holders to contract their way out of the statutorily imposed risk that patent litigation could lead to invalidation of the patent while claiming antitrust immunity for that private contract. . . . [T]his standard effectively bars considering whether the agreement might violate the antitrust laws, and so offers no protection to the public interest in eliminating undeserved patents.

Brief for the United States as Amicus at 14-15.[19] While acknowledging that patent-holders are entitled to settle disputes over the validity of their patent, the United States proposes that excessive reverse payment settlements be deemed presumptively unlawful unless a patent-holder can show that settlement payments do not greatly exceed anticipated litigation costs. *Id.* at 27-32.

---

19. Amici similarly argue that the *Tamoxifen* court's permissive approach to reverse payments offers protection to patent holders beyond that envisioned by patent law, is inconsistent with the principle that antitrust cases be decided "based upon demonstrable economic effect rather than . . . formalistic line drawing," Brief for AAI as Amicus at 5, (quoting *Continental T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36 (1977)), and did not give sufficient consideration to the public interest in "authoritative testing of patent validity." Brief for Nat'l Assoc. of Chain Drug Stores, Inc. as Amicus at 20 (quoting *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 343 (1971)).

Second, there is evidence that the practice of entering into reverse exclusionary payment settlements has increased since we decided *Tamoxifen*. Prior to our *Tamoxifen* decision, there were fourteen settlements of Hatch-Waxman lawsuits, none of which involved reverse payments to a generic manufacturer. Brief for American Antitrust Institute as Amicus at 3 (citing Fed. Trade Comm'n, *Generic Drug Entry: Prior to Patent Expiration* 31-32, 34 (July 2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf). After *Tamoxifen*, however, plaintiffs represent that twenty of twenty-seven Hatch-Waxman settlements have involved reverse payments.

Third, after *Tamoxifen* was decided, a principal drafter of the Hatch-Waxman Act criticized the settlement practice at issue here. *See* 148 Cong. Rec. S7565 (July 30, 2002) (remarks of Sen. Hatch) ("As coauthor of the [Hatch-Waxman Act], I can tell you that I find these type[s] of reverse payment collusive arrangements appalling"); see also 146 Cong. Rec. E1538-02 (Sept 20, 2000) (remarks of Rep. Waxman) ("[R]equir[ing] companies seeking to reach secret, anticompetitive agreements to disclose them to the FTC . . . . [would] ensure that existing antitrust and drug approval laws are enforced to the letter.").[20]

20. We are not insensitive to "the oft-repeated warning that the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one." *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 117 (1980) (quotation marks omitted). However, remarks by an Act's author do not trigger the typical concern about post-enactment legislative history, namely that "the losers in the legislative arena hope to persuade the courts to give them the victory after all." Richard A. Posner, *How Judges Think* 344 (2008).

Fourth and finally, the *Tamoxifen* panel appears to have relied on erroneous characterization of the Hatch-Waxman Act. *Tamoxifen* was based in no small part on the panel majority's statement that reverse exclusionary settlements "open[ ] the [relevant] patent to immediate challenge by other potential generic manufacturers which did indeed follow – spurred by the additional incentive (at the time) of potentially securing the 180-day exclusivity period available upon a victory in a subsequent infringement lawsuit..." 466 F.3d at 214. If understood as a legal conclusion that the statutory exclusivity period cedes to the first ANDA filer to successfully defend, was erroneous. *See* Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement As a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1583-86 (2006); *cf.* 21 C.F.R. § 314.107(c)(1)-(2) (only first-filer eligible for exclusivity period); 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873 (Aug. 6, 1999) (revisiting and re-endorsing FDA interpretation of exclusivity provisions); 21 U.S.C. § 355(j)(5)(D)(iii) (codifying FDA interpretation).[21]

In addition, unlike *Tamoxifen*, which was decided at the 12(b)(6) stage, this case involves a summary judgment decision based on a full record. This case could

---

21. Although the panel majority might conceivably be understood to have described only the *beliefs* of ANDA filers before 2003, we think that the above-quoted language is more naturally read as a legal characterization of the Hatch-Waxman Act's exclusivity provisions.

provide our full Court with an opportunity to revisit the issues in play in *Tamoxifen* and to analyze the competing interests that underlie antitrust challenges to reverse payment settlements in light of the full record and the arguments of the parties and amici, including the United States, that have been raised in this appeal. We therefore invite plaintiffs-appellants to petition for in banc rehearing.

CONCLUSION

In sum, as long as *Tamoxifen* is controlling law, plaintiffs' claims cannot survive. Accordingly, we AFFIRM the judgment of the district court. However, we believe there are compelling reasons to revisit *Tamoxifen* with the benefit of the full Court's consideration of the difficult questions at issue and the important interests at stake. We therefore invite the plaintiffs-appellants to petition for rehearing in banc.

APPENDIX C — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT, EASTERN DISTRICT OF NEW YORK DATED MARCH 31, 2005

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

1:00-MDL-1383
(DGT)

IN RE CIPROFLOXACIN HYDROCHLORIDE ANTITRUST LITIGATION

MEMORANDUM AND ORDER

TRAGER, J.

This action involves agreements between the brand-name manufacturer of the widely used antibiotic ciprofloxacin hydrochloride ("Cipro") and potential generic manufacturers of Cipro. The brand-name manufacturer, Bayer AG, a German company, and its American subsidiary, Bayer Corporation (collectively, "Bayer") and the generics, Barr Laboratories, Inc. ("Barr"); The Rugby Group, Inc. ("Rugby"); Hoechst Marion Roussel, Inc. ("HMR"); and Watson Pharmaceuticals, Inc. ("Watson") (collectively, "generic defendants")[1] entered into agreements that Direct

1. Barr and Rugby are in the business of, *inter alia*, manufacturing and marketing generic drugs. Rugby was the U.S. generic drug subsidiary of HMR until February 1998, when Rugby was acquired by Watson, a company that produces and distributes generic and brand-name drugs. Watson is not a signatory to any of the allegedly unlawful agreements.

Appendix C

Purchaser Plaintiffs ("direct plaintiffs") and Indirect Purchaser Class Plaintiffs ("indirect plaintiffs") allege prevented competition in the market for Cipro in violation of federal and state antitrust laws.[2] Plaintiffs previously filed motions for partial summary judgment seeking a determination that these agreements were *per se* unlawful under Section 1 of the Sherman Act, 15 U.S.C. § 1 (and various state antitrust and consumer protection laws), which were denied. Subsequently, indirect plaintiffs amended their complaint to add a new count, Count V, alleging *Walker Process*-type[3] and sham litigation antitrust violations under state law.

Bayer and generic defendants have now each filed motions for summary judgment asserting that these agreements do not violate Section 1 of the Sherman Act because they had no anti-competitive effects beyond the

---

2. The generic defendants, together with Bayer, will be referred to as the "defendants," while direct plaintiffs and indirect plaintiffs will be referred to as "plaintiffs."

3. In *Walker Process Equipment, Inc. v. Food Machinery & Chem. Corp.*, 382 U.S. 172, 177, 86 S.Ct. 347, 15 L.Ed.2d 247 (1965), the Supreme Court first recognized an antitrust cause of action based on assertion of a patent known to have been obtained by fraud on the United States Patent and Trademark Office ("PTO"), provided that the other elements of a Sherman Act claim are present. Such claims are commonly referred to as *Walker Process* claims. Because indirect plaintiffs are asserting their claims under state law and because they have pointed to no state law explicitly recognizing an antitrust claim for assertion of a patent obtained by fraud, their claim is referred to as a *Walker Process*-type claim.

scope of Bayer's patent on ciprofloxacin, while direct plaintiffs have filed a motion for partial summary judgment arguing that the agreements meet the "anti-competitive conduct" requirement of Section 1 of the Sherman Act and the "antitrust injury" requirement of the Section 4 of the Clayton Act. Bayer has also filed two motions relating to Count V of indirect plaintiffs' second amended complaint ("Count V"). The first, a motion to dismiss Count V, is made on the grounds that indirect plaintiffs' state law *Walker Process*-type claim is preempted by federal patent law and is barred by the statute of limitations. The second, filed in the event Count V is not dismissed, is a motion for summary judgment on Count V on the grounds that indirect plaintiffs have failed to demonstrate that any misrepresentations or omissions made by Bayer in prosecuting its patent were so highly material that the patent would not have issued but for the alleged deceptions and that plaintiffs' sham litigation claim fails as a matter of law. Finally, HMR and Rugby have filed a motion for summary judgment that indirect plaintiffs' claims against them are barred by the doctrine of *Illinois Brick*[4] and that any rights assigned to indirect plaintiffs do not include claims against HMR.

---

4. Under *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 97 S.Ct. 2061, 52 L.Ed.2d 707 (1977), indirect purchasers are barred from recovering damages for monopolistic overcharges under federal antitrust law.

Appendix C

Background

The statutory and regulatory background, as well as the circumstances of this case, were fully described in the court's initial opinion, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 166 F. Supp. 2d 740 (E.D.N.Y. 2001) ("*Cipro I*") (granting certain plaintiffs' motions to remand to state court). The developments in the case were further discussed and analyzed in a second opinion, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003) ("*Cipro II*") (granting in part and denying in part defendants' motions to dismiss, and denying plaintiffs' motion for partial summary judgment asserting that the agreements constituted *per se* violations of the antitrust laws). Familiarity with those decisions is presumed, and what follows is a summary of only those facts necessary for the resolution of the pending motions.

Bayer is the assignee of U.S. Patent No. 4,670,444 ("the '444 Patent"), a compound patent which claims the chemical entity that is the active ingredient in Cipro – ciprofloxacin hydrochloride—and all its generic equivalents. *See Cipro II*, 261 F. Supp. 2d at 249 ("A patent on a compound that is the only active ingredient in a drug covers all generic versions of that drug . . . . regardless of how formulated, processed or delivered . . . ."). The '444 Patent issued on June 2, 1987 from patent application Ser. No. 614,923 ("the '923 application"), which was filed on May 29, 1984. The '923 application was filed as a continuation-in-part[5] of Ser.

5. A continuation-in-part application is an application that claims priority to and includes the subject matter of at least part of an earlier-filed application.

No. 292,560 ("the '560 application"), which was filed on August 13, 1981, and Ser. No. 436,112 ("the '112 application"), which was filed on October 22, 1982. *See* App. to Aff. of Paul J. Skiermont in Support of Bayer's Mot. for Partial Summ. J. on Count V of the Indir. Pls.' Proposed Second Am. Consol. Class Action Compl. ("Bayer Count V App."), Ex. 1.

In October 1987, Bayer's predecessor, Miles, Inc., obtained FDA approval to market Cipro in the United States. *Cipro II*, 261 F. Supp. 2d at 194. From 1987 until 2004, Bayer was the only producer of Cipro in the United States. *Id.* On October 22, 1991, Barr filed Abbreviated New Drug Application ("ANDA") 74-124 for permission to market a generic version of Cipro, and included a Paragraph IV certification, seeking permission to market its generic drug before expiration of the '444 Patent on the grounds that the patent was invalid and unenforceable. *Id.* Because the '444 Patent claims the active ingredient in Cipro and because Barr was required in its ANDA to certify that its generic version of Cipro was bioequivalent to Bayer's Cipro, there is no dispute that Barr's product would have infringed Bayer's patent. *Cipro II*, at 249; *see also* App. to Aff. of Paul J. Skiermont in Support of Bayer's Mot. for Partial Summ. J. on Pls. Claims Under the Sherman Act and Corr. State Law Claims ("Bayer Sherman Act App."), Tab 5 (Stipulation and Order (Barr's stipulation that it infringed the '444 Patent)).

Pursuant to the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355,

on December 6, 1991, Barr notified Bayer of its ANDA IV filing, and on January 16, 1992, Bayer sued Barr for patent infringement in the Southern District of New York, where the case was assigned to Judge Whitman Knapp. *Cipro II*, 261 F. Supp. 2d at 194. In January 1996, Bayer and Barr filed cross-motions for partial summary judgment, which Judge Knapp denied in an order and opinion dated June 5, 1996. *Id.* at 195. In March 1996, while these cross-motions were *sub judice*, Barr agreed to share equally any profits from the eventual marketing and/or distribution of Cipro with Rugby, which was then a subsidiary of HMR, and, in return, Rugby agreed to finance a portion of the costs and expenses of the patent litigation against Bayer. *Id.*

On January 8, 1997, just weeks before trial was scheduled to begin, Bayer and Barr reached a settlement of the patent litigation, with Bayer entering into three separate agreements with Barr, HMR and Rugby, and Bernard Sherman and Apotex, Inc. (collectively, the "Settlement Agreements") and a supply agreement with Barr and HMR (the "Supply Agreement") (collectively with the Settlement Agreements, the "Agreements"), the terms of which give rise to the plaintiffs' claims of Sherman Act violations. *Id.* at 195-96. Under the Barr Settlement Agreement, Bayer paid Barr $49.1 million and, in return, required Barr to amend its ANDA from a Paragraph IV certification to a Paragraph III certification, which would permit it to market a generic form of Cipro only upon the expiration of the '444 Patent. *Id.* at 196. However, the Barr Settlement Agreement preserved the option

for Barr to re-amend to a Paragraph IV certification (for the purpose of reclaiming the 180-day exclusivity period that is awarded to a first-filer of an ANDA IV) in the event the '444 Patent were subsequently declared invalid or unenforceable by a court of competent jurisdiction. Bayer Sherman Act App., Ex. 16 ¶ 5(a); *see Cipro II*, 261 F. Supp. 2d at 243-47.

Under the terms of the Supply Agreement, Barr and HMR agreed not to manufacture or have manufactured a generic form of Cipro in the United States. *Cipro II*, 261 F. Supp. 2d at 196. The Supply Agreement further provides that Bayer will either supply Bayer-manufactured Cipro to Barr, HMR and Rugby for distribution in the United States, or make quarterly payments to Barr from January 1998 through December 2003, at which time the '444 Patent was due to expire. *Id.* Bayer opted to make the payments, which, by December 2003, when added to the initial $49.1 million payment, totaled approximately $398 million. *Id.*

Bayer and Barr also entered into a Consent Judgment, terminating the litigation, in which Barr affirmed the validity and enforceability of the '444 Patent and admitted infringement. *Id.* at 196; Bayer Sherman Act App., Ex. 18. The Consent Judgment was signed by Judge Knapp, but made no mention of any payments from Bayer to Barr. *Id.*

Six months after settling with Barr, in July 1997, Bayer submitted the '444 Patent to the Patent and Trademark Office ("PTO") for reexamination. During

the reexamination, Bayer amended certain of the claims of the '444 Patent and cancelled others, after which the PTO reaffirmed the patent's validity, including the validity of claim 12, which was not substantively amended and which all parties agree covers ciprofloxacin hydrochloride. *Id.* at 197; Bayer's Reply Mem. in Supp. of Its Mot. for Partial Summ. J. on Count V of the Indirect Purchaser Class Pls.' Proposed Second Am. Consolidated Class Action Compl. ("Bayer's Count V Reply Mem.") at 19; Bayer Sherman Act App., Ex. 5; App. to Aff. of Paul J. Skiermont in Support of Bayer's Mot. for Partial Summ. J. on Count V of the Indir. Pls.' Proposed Second Am. Consol. Class Action Compl. ("Bayer Count V S. J. App."), Ex. 9. Thereafter, four other generic companies - Schein, Mylan, Carlsbad and Ranbaxy - each challenged the reexamined '444 Patent by filing ANDA IVs for Cipro. *Cipro II*, 261 F. Supp. 2d at 197. Bayer defeated Schein and Mylan's validity challenges on summary judgment, and those decisions were upheld by the Court of Appeals for the Federal Circuit. *Id.* at 201. The Carlsbad case proceeded to a nine-day bench trial, after which the judge rejected Carlsbad's invalidity argument and upheld the validity of the '444 Patent. *See* Bayer Count V App., Exs. 15 and 16 (*Bayer AG v. Carlsbad Tech., Inc.*, No. 01-cv-0867-B, slip op. at 5-13 (S.D. Cal. June 7, 2002 and Aug. 7, 2002)). Ranbaxy's challenge was dismissed as moot after Ranbaxy withdrew its Paragraph IV certification. *Cipro II*, 261 F. Supp. 2d at 197.

Appendix C

Discussion

(1)

Sherman Act Motions for Summary Judgment

The *Cipro II* decision made clear that Barr's agreement with Bayer not to sell ciprofloxacin in exchange for the exclusion payments, also commonly known as reverse or exit payments,[6] did not constitute a *per se* violation of the Sherman Act because the exclusionary effect of the Agreements was within the scope of the '444 Patent. Direct plaintiffs now move for summary judgment that the exclusion-payment scheme meets the "anti-competitive conduct" requirement of Section 1 of the Sherman Act under a rule of reason analysis, while both Bayer and generic defendants move for summary judgment that the Agreements had no anti-competitive effects that are actionable under the Sherman Act because they were within the scope of the '444 Patent. Resolution of this issue requires a close look at the intersection of patent and antitrust laws.

The rule of reason analysis involves a three-step process. First, the plaintiff must prove that "the challenged action has had an *actual* adverse effect on

6. In briefing these motions, the parties have sometimes referred to these payments as "reverse" payments. Adoption herein of the "exclusion payments" nomenclature is made for ease of reference, and in recognition that the payments, whatever they are called, are made in exchange for a competitor's exit or exclusion from the relevant market.

competition as a whole in the relevant market." *K.M.B. Warehouse Distributors, Inc. v. Walker Mfg. Co.*, 61 F. 3d 123, 127 (2d Cir. 1995) (emphasis in original) (quoting *Capital Imaging Assocs. v. Mohawk Valley Med. Assocs.*, 996 F.2d 537, 543 (2d Cir.), *cert. denied*, 510 U.S. 947, 114 S.Ct. 388, 126 L.Ed.2d 337 (1993)). Next, "the burden shifts to the defendant to establish the 'pro-competitive redeeming virtues' of the action." *Id.* If the defendant succeeds, the burden shifts back to the plaintiff to "show that the same procompetitive effect could be achieved through an alternative means that is less restrictive of competition." *Id.*[7], [8]

---

7. Summary judgment is appropriate only in those cases where there is no genuine issue of material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). Here, Bayer, generic defendants and direct plaintiffs have each filed motions for summary judgment on the issue of whether the Bayer/Barr settlement agreements had an anti-competitive effect. The burden of proving anti-competitive effects lies with the plaintiffs in the first instance, and, as discussed *infra*, plaintiffs have shown no anti-competitive effects beyond the scope of the '444 Patent. The analysis with respect to those anti-competitive effects that are within the scope of the '444 Patent (and which all parties agree were present) constitutes a pure discussion of law without regard to burdens of proof.

8. A recent decision by the Eleventh Circuit questions the appropriateness of the *per se* versus rule of reason approach for claims of antitrust violations involving patents. *See Schering-Plough v. Federal Trade Comm'n*, __ F.3d __, __, 2005 WL 528439, at *7 (11th Cir. Mar. 8, 2005). The Eleventh Circuit's opinion can fairly be read as breaking the first step of a rule of reason analysis – assessing the actual adverse effects on competition –

(Cont'd)

Appendix C

a. Relevant market

Taking these steps one at a time, the first question is whether plaintiffs have shown that the Agreements had an actual adverse effect on competition in the relevant market. Traditionally, the starting point of an antitrust inquiry is the definition of the relevant market. *See, e.g., Geneva Pharma. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 496 (2d Cir. 2004) ("Evaluating market power begins with defining the relevant market."). The purpose of this inquiry is to determine whether defendants possess market power, *i.e.*, the ability to lessen or destroy competition, which, while not the *sine qua non* of a violation of Section 1 of the Sherman Act, is "a highly relevant factor in rule of reason analysis because market power bears a particularly strong relationship to a party's ability to injure competition." *Capital Imaging*, 996 F.2d at 546. The parties dispute whether the relevant market comprises only ciprofloxacin, as plaintiffs have asserted in their complaint, *see* Indir. Pls.' Second Am. Consol. Class

---

(Cont'd)

into three steps to determine whether there are any anti-competitive effects that exceed the scope of the patent. Regardless of whether the Eleventh Circuit intended to jettison the rule of reason analysis in the patent context or simply refine the analysis, the case at bar will be considered under this court's prior opinion adopting the rule of reason mode of analysis. *See Cipro II*, 261 F. Supp. 2d at 256-57. It would be inappropriate not to address the issue accordingly, not least because the parties have briefed the issue in light of that analysis. In any event, the same result would be reached under either analytical approach.

Action Compl. ¶ 34, or includes other drugs in the same molecular family as ciprofloxacin (flouroquinolones), which Bayer contends compete with ciprofloxacin in the U.S. antibiotic market, *see* Bayer Defs. ' Mem. of Law in Opp'n to Direct Purchaser Pls.' Mot. for Partial Summ. J. ("Bayer's Opp. Mem."), at 26-29.

Plaintiffs assert that it is unnecessary to show a relevant market in this case because there exists direct evidence of anti-competitive effects. Mem. in Support of Direct Purchaser Pls.' Mot. for Partial Summ. J. ("Dir. Pls.' Mem."), at 25. In general, to sidestep the traditional relevant market analysis, a plaintiff must show by direct evidence "an actual adverse effect on competition, such as reduced output." *Geneva v. Barr*, 386 F.3d at 509 ("If plaintiff can demonstrate an actual adverse effect on competition, such as reduced output, . . . there is no need to show market power in addition.") (citing *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 460-61, 106 S.Ct. 2009, 2019, 90 L.Ed.2d 445 (1986); *K.M.B. Warehouse*, 61 F.3d at 128-29). The reason for permitting this alternative showing is simply that the purpose of an inquiry into market power "is to determine whether an arrangement has the potential for genuine adverse effects on competition." *FTC v. Indiana Fed'n of Dentists*, 476 U.S. at 460, 106 S.Ct. at 2019. In effect, market power is "but a 'surrogate for detrimental effects.'" *Id.*, 476 U.S. at 461, 106 S.Ct. at 2019 (quoting 7 P. Areeda, Antitrust Law ¶ 1511, p. 429 (1986)).

For their direct evidence showing, direct plaintiffs point to government and academic studies concluding

that purchasers derive substantial savings from the availability of generic drugs; internal analyses by the brand name and generic manufacturers themselves forecasting significant price reductions once generic drugs become available; and sales data showing the actual effects of competition once generic Cipro was introduced into the market. Dir. Pls.' Mem. at 25-31. In particular, direct plaintiffs rely on a 1998 study by the Congressional Budget Office comparing brand-name and generic prices for twenty-one different drugs that faced generic competition between 1991 and 1993, which found that the average retail price of a prescription for a generic drug in 1994 was less than half the average brand-name drug price. App. in Support of Decl. of Monica L. Rebuck for Dir. Pls. I Mot. for Partial Summ. J. (Dir. Pls. I Summ. J. App.), Tab 5 (Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, at 28-31 (July 1998) ("CBO Study")). Another study cited by ,direct plaintiffs found that by 2000, the average brand-name prescription cost 340 percent more than its generic equivalent ($65.29 versus $19.33). Dir. Pls. Summ. J. App., Tab 20 (Kirkling et al., *Economics and Structure of the Generic Pharmaceutical Industry*, 41 J. Amer. Pharm. Assoc. 578, 579 (2001)).

These studies notwithstanding, the significant price differences actually suggest a finding contrary to the one implied by plaintiffs. Namely, brand-name pharmaceuticals and their generic counterparts might not always compete in the same markets at all because,

based on the higher prices of the brand-name drugs, there is less cross-elasticity of demand than one might expect. (If there were, the prices for brand-name drug prices should fall and be closer to that of generics). Indeed, the CBO Study cited by plaintiffs indicates that prices for brand-name drugs continue to rise faster than inflation even after generic competition begins. CBO Study at 30-31. The Second Circuit recently relied on similar price differential data to reach a particularly narrow market definition in *Geneva v. Barr*, 386 F.3d at 496-500. In that case, the court, relying on the factors set forth in *Brown Shoe Co. v. United States*, 370 U.S. 294, 325, 82 S.Ct. 1502, 1524, 8 L.Ed. 1264 (1956), defined the market as limited to *generic* warfarin sodium. *Id.*; *see also Asahi Glass Co., Ltd. v. Pentech Pharma., Inc.*, 289 F. Supp. 2d 986, 995-96 (N.D. Ill. 2003) (Posner, J., sitting by designation) (noting that paroxetine, the active ingredient in Paxil, competes with molecules that are the basis for other antidepressant drugs such as Prozac and Zoloft, but reserving the possibility that paroxetine might still warrant treatment as a separate market).

Despite the fact that brand-name pharmaceuticals are apparently able to maintain significantly higher prices even after generic entry, the parties' internal analyses prepared at the time the Agreements were entered into confirm that both Bayer and Barr expected Bayer to lose significant sales once generic competition began, with Bayer estimating losses of between $510 million and $826 million in Cipro sales during the first two years of generic competition, depending on the

number of generic manufacturers entering the market. Dir. Pls.' Summ. J. App., Tab 47A, at BCP4630078. Another contemporaneous internal Bayer document estimated Bayer's losses due to a potential adverse judgment in the '444 Patent litigation at $1.679 billion net present value. Dir. Pls.' Summ. J. App., Tab 47D at BCP-P-0001572-004(2). Barr, similarly, projected that it and other generic manufacturers would capture a large percentage of the market for ciprofloxacin within the first two years of generic competition, and would enter the market at a 30 percent discount off Bayer's price. Dir. Pls.' Summ. J. App., Tab 36A at BLI-003560.

Finally, direct plaintiffs point to post-generic entry data showing that Barr in fact did capture more than 50 percent of Bayer's Cipro sales soon after entering the market, and that it initially priced its generic ciprofloxacin at only 8 percent below Bayer's Cipro product. Dir. Pls.' Summ. J. App., Tab 35 (Expert Report of Jeffrey J. Leitzinger, Ph.D., at 38 n.93). Direct plaintiffs also note that the Amended and Restated Supply Agreement between Bayer and Barr, dated August 28, 2003, which provides for Bayer to continue supplying ciprofloxacin to Barr for resale after expiration of the pediatric marketing exclusivity extension that Bayer obtained pursuant to 21 U.S.C. § 355a, sets drastically reduced prices for Cipro after the commencement of open generic competition. Dir. Pls.' Summ. J. App., Tab 43A at BCP4660023. For example, a 100-pill bottle of oral, 500-mg ciprofloxacin that cost Barr $321.96 before the beginning of open generic competition would cost only $14.30 after the expiration

of Bayer's pediatric exclusivity, a 95 percent difference in price. *Id.* Bayer has admitted that the purpose of the price drop was to allow Barr to compete with additional generic manufacturers who would then be entering the market. Dir. Pls.' Summ. J. App., Tab 80 at 112.

Bayer discounts the import of these facts, insisting instead that Cipro competes in the larger market of flouroquinolones, which includes other drugs such as Levaquin, Floxin and Noroxin, within which Cipro has been losing market share, from 75 percent in 1996 to 43 percent in 2001. Bayer's Opp. Mem. at 28-29. Bayer maintains that a properly defined market must include all quinolone antibiotics and that defendants did not possess enough market power to control prices or exclude competition within that larger market. *Id.* at 29.

Although evidence that Bayer charged high prices for Cipro "may of course be indicative of monopoly power," it is not necessarily conclusive in the absence of any analysis of Bayer's costs. *See, e.g., Geneva v. Barr*, 386 F.3d at 500. Plaintiffs have provided neither evidence of Bayer's costs nor any direct evidence that defendants restricted output. However, the pricing strategy encompassed in the Amended and Restated Supply Agreement compels an inference that Bayer was reaping an abnormally high price-cost margin, given the 95 percent price drop that was to occur almost a full year in the future for an identical quantity of an identical strength of the identical drug. Dir. Pls.' Summ. J. App., Tab 43A at BCP4660023. Given Bayer's obvious ability

to control prices, and its admission that it did not anticipate a commensurate drop in its own production costs for Cipro,[9] it is reasonable to accept plaintiffs' contention and conclude both that the relevant market is for ciprofloxacin and that Bayer had market power within that market.

b. Adverse effect on competition

The ultimate question - and this is the crux of the matter - is not whether Bayer and Barr had the power to adversely affect competition for ciprofloxacin as a whole, but whether any adverse effects on competition stemming from the Agreements were outside the exclusionary zone of the '444 Patent. It goes without saying that patents have adverse effects on competition. *See Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806, 816, 65 S.Ct. 993, 998, 89 L.Ed. 1381 (1945) (A patent "is an exception to the general rule against monopolies and to the right to access to a free and open market."); *Schering-Plough*, ____F.3d____ at, 2005 WL 528439, at *7 ("By their nature, patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive

9. Bayer admitted at oral argument that its estimated costs of production did not change after the exclusivity period, but contends that its marketing costs were projected to drop sharply after generic entry. It is understandable that Bayer would choose to spend less to promote Cipro at a time when its marketing efforts would not redound exclusively to its own benefit, but a drop in such discretionary spending only further illustrates the degree to which Bayer controlled its own profit margin.

effect is already present."). However, any adverse effects within the scope of a patent cannot be redressed by antitrust law. *See United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1127 (D.C. Cir. 1981) ("[T]he conduct at issue is illegal if it threatens competition in areas other than those protected by the patent and is otherwise legal."); *see also United States v. General Electric Co.*, 272 U.S. 476, 485, 47 S.Ct. 192, 195, 71 L.Ed. 362 (1926); *E. Bement & Sons v. National Harrow Co.*, 186 U.S. 70, 91, 22 S.Ct. 747, 755, 46 L.Ed. 1058 (1902). The '444 Patent gave Bayer the right to exclude competition entirely for ciprofloxacin for the term of the patent, and any conduct within the scope of the patent is exempt from antitrust scrutiny. *See Cipro II*, 261 F. Supp. 2d at 248 ("[A] patent holder does not run afoul of the Sherman Act unless the patent holder acts beyond the confines of the patent monopoly."). Defendants argue that a determination that the Agreements do not restrict competition beyond the scope of the claims of the '444 Patent ends the inquiry as to anti-competitive effects. Plaintiffs, on the other hand, argue that the exclusionary power of the patent for purposes of the anti-competitive effects analysis should be tempered by its potential invalidity.

i. The validity inquiry

While there have been to date only a handful of cases discussing the legality of patent settlement exclusion payments, some courts and commentators have dealt with the questions of whether and to what extent the validity of the patent should be a factor in appraising

the legality of an exclusion payment, and what sort of inquiry into validity an antitrust court should make. The Second Circuit has not yet addressed these issues, but two federal circuits, two district courts (including one on which Judge Posner sat by designation) and the Federal Trade Commission ("FTC") have considered them. Although those courts have come to different conclusions regarding the legality of exclusion payments at issue in those cases, they have generally agreed that an antitrust court need not make an independent assessment of the underlying patent's validity.

The Eleventh Circuit's approach in *Valley Drug*

The Eleventh Circuit in *Valley Drug Co. v. Geneva Pharma., Inc.*, 344 F.3d 1294 (11th Cir. 2003), held that to the extent the effects of the subject settlement agreements are within the scope of the exclusionary potential of the patent, such effects are not subject to *per se* (or rule of reason) antitrust condemnation, even where the patent is later held invalid. *Valley Drug*, 344 F.3d at 1311. The two agreements at issue in that case were between Abbott, manufacturer of the pioneer drug Hytrin, and two of its generic competitors - Geneva and Zenith. *Id.* at 1296. Abbott held multiple patents on Hytrin, a drug containing terazosin hydrochloride, which is used to treat hypertension and enlarged prostate, and Geneva filed several ANDA IVs on Hytrin over a period of years. *Id.* at 1298. Zenith, meanwhile, had also filed an ANDA IV on Hytrin, which was pending when two additional patents relating to the active ingredient in Hytrin were issued to Abbott. *Id.* Abbott

listed the new patent information with the FDA, which then required Zenith to make a certification with respect to the newly-issued patents. *Id.* Rather than comply, Zenith filed suit against Abbott to force Abbott to delist the new patents, alleging that Abbott listed them with the knowledge that they were not applicable to Hytrin. *Id.*

On March 31, 1998, Abbott and Zenith entered an agreement settling their delisting and infringement dispute, under which Zenith agreed not to sell or distribute any generic terazosin hydrochloride product until a third party entered the market or until one of Abbott's patents expired, in exchange for payments by Abbott of $6 million every three months. *Id.* at 1300. The next day, Abbott entered a similar agreement with Geneva whereby Geneva agreed not to sell or distribute any generic terazosin hydrochloride product until one of Abbott's patents expired, a third party entered the market or Geneva obtained a final court judgment from which no further appeal could be taken that its terazosin products did not infringe on of Abbott's patents or that the patent was invalid. *Id.* In exchange, Abbott agreed to pay Geneva $4.5 million per month. *Id.* Geneva subsequently prevailed in the patent infringement suit Abbott had filed against it, obtaining a judgment on September 1, 1998 that the patent at issue in that case was invalid. *Id.* at 1301.

The district court concluded that Abbott's agreements with Zenith and Geneva were *per se* violations of Section 1 of the Sherman Act, holding that

the exclusionary effect of the agreements constituted an allocation of the market between horizontal competitors. *Id.* at 1304. The Eleventh Circuit reversed, however, rejecting the argument "that the agreements by Geneva and Zenith not to produce infringing products are subject) to *per se* condemnation and treble-damages liability merely because the '207 patent was subsequently declared invalid." *Id.* at 1306. The court ruled that "the mere subsequent invalidity of the patent does not render the patent irrelevant to the appropriate antitrust analysis." *Id.* at 1306-07. The court invoked the rationale of Justice Harlan's concurrence in *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 179-80, 86 S.Ct. 347, 351-52, 15 L.Ed.2d 247 (1965): "[T]o hold, as we do not, that private antitrust suits might also reach monopolies practiced under patents that for one reason or another may turn out to be voidable under one or more of the numerous technicalities attending the issuance of a patent, might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits." *Id.* at 1307. The court accordingly reserved any *post hoc* validity analysis for those cases in which the patent was procured by fraud or known by the patentee to be invalid. *Id.* at 1307.

The court concluded that " [p]atent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the

mere invalidity of the patent." *Id.* at 1308. The court held open the possibility that the size of the payment to refrain from competing could be evidence of a lack of faith in the validity of the patent or evidence that the patent was obtained by fraud but, citing this court's decision in *Cipro II*, noted that the asymmetries of risk inherent in a Hatch-Waxman patent litigation and the high profits at stake could induce even a confident patentee to pay a substantial sum in settlement. *Id.* at 1309-10.

The *Valley Drug* court thus took the position that an antitrust court need not consider the potential invalidity of the patent in an exclusion-payment settlement, except in those extreme cases involving fraud on the Patent Office or assertion of a patent known to be invalid, *i.e.*, in circumstances giving rise to an allegation of *Walker Process* fraud or sham litigation. However, the court went on to direct the district court on remand to evaluate the defendants' claim that the exclusionary effects of the patent and the agreements were coextensive because certain provisions of the agreements were analogous to a consensual preliminary injunction and stay of judgment pending appeal. *Id.* at 1312. The court instructed that this evaluation should include a comparison between "the provisions of the agreement and the protections afforded by the preliminary injunction and stay mechanisms," and, furthermore, that the "likelihood of Abbott's obtaining such protections" should be considered. *Id.*

On remand, the district court interpreted the Eleventh Circuit's instructions as requiring an analysis

of the likelihood that Abbott would have won a preliminary injunction at the time the agreements were executed, which it construed as requiring an analysis of whether Abbott would have been able to show that its patent was likely valid, rather than an analysis simply of whether the patent claims covered Abbott's product. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1295 (S.D. Fl. 2005). The district court proceeded to determine the likely validity of the patent at the time the agreements were entered, employing the standards applicable to a preliminary injunction analysis. *Id.* at 1303-07. The district court ultimately concluded that Abbott would likely not have been able to show that its patent was likely valid at the preliminary injunction stage of its suit against Geneva and, therefore, held that the Geneva agreement went beyond the exclusionary zone of the patent and was a *per se* violation of the Sherman Act.

It is not certain that the district court correctly interpreted the Eleventh Circuit's opinion, and, indeed, the Eleventh Circuit seems to have expressed some doubt on that point in an unrelated opinion. *See Schering-Plough*, ____F.3d____ at 2005 WL 528439, at *7 n.14 ("On remand, the district court in *Valley Drug* still applied a *per se* analysis . . . ."). In any event, the implication of the district court's reasoning conflicts with the proposition already rejected in *Cipro, II* - that the legality of the Agreements is contingent on Barr's chances of having won at trial. *See Cipro II*, 261 F. Supp. 2d at 202 ("[P]laintiffs cannot avoid dismissal based on a claim of injury-in-fact that relies on the hope that Barr would have prevailed in its suit against Bayer.").

Appendix C

The Sixth Circuit's approach in *Cardizem*

The Sixth Circuit, in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), also eschewed an analysis of the patent's validity in analyzing the anti-competitive effects of an exclusion-payment patent settlement agreement, although that court, unlike this one, concluded that such a settlement was a *per se* violation of the Sherman Act without considering the scope of the underlying patent right. The agreement at issue in that case, however, contained provisions that clearly exceeded any competitive restrictions accruing to the defendants under patent law, particularly because the settling generic manufacturer, Andrx, did not relinquish its claim to 180 days of generic marketing exclusivity under the Hatch-Waxman Act. That is, a term of the agreement required that Andrx maintain its status as first-filer of an ANDA IV even after entering the agreement with the brand-name manufacturer. *In re Cardizem*, 332 F.3d at 902. Andrx's refusal to amend its ANDA to give up the exclusivity claim resulted in a market bottleneck since no other generic manufacturer could come to market until at least 180 days after Andrx began marketing the drug, a trigger that was postponed indefinitely by the settlement. *Id.* at 907. Thus, the brand-name manufacturer used the agreement to effectively bar third parties from mounting challenges to its patent - a power clearly not within the exclusionary power of a patent. Therefore, although the Sixth Circuit arrived at a different conclusion regarding *per se* liability, its approach was consistent with the position

taken by this court in *Cipro II* - namely, that a patent holder cannot exploit the Hatch-Waxman provisions to create a bottleneck that indefinitely excludes subsequent generic challengers from the market. It is also clear that the Sixth Circuit did not engage in an after-the-fact analysis of the patent's likely validity in reaching its determination.

Judge Posner's approach in *Asahi Glass*

Judge Posner, sitting by designation for the Northern District of Illinois, adopted similar reasoning to that of the Eleventh Circuit in *Valley Drug* in analyzing the merits of an antitrust action brought by a supplier to a generic pharmaceutical company that was shut out of the market for paroxetine hydrochloride (sold as the antidepressent Paxil) by a settlement agreement between the generic and the brand-name manufacturer. *Asahi Glass*, 289 F. Supp. 2d at 992-93. The agreement settled a Hatch-Waxman patent litigation and stipulated that the brand-name manufacturer would provide the finished drug product free of charge to the generic company, which would then sell it as an unbranded version of Paxil and pay a sizeable royalty to the brand-name manufacturer. The plaintiff, which had previously anticipated selling the active ingredient for the drug to the generic manufacturer, found itself without a customer, since the generic manufacturer had no incentive to pay for that which it was already getting for free from the brand-name drug maker. The plaintiff sued both parties to the agreement, alleging that the

agreement violated Section 1 of the Sherman Act. Judge Posner dismissed the complaint on the ground that the agreement was a legitimate settlement of a patent infringement suit. *Id.* at 991.

Commenting on the hesitation of an antitrust court to delve into the merits of a predicate patent suit and its potential effect on a settlement agreement, Judge Posner noted:

> [T]he private thoughts of a patentee, or of the alleged infringer who settles with him, about whether the patent is valid or whether it has been infringed is not the issue in an antitrust case. A firm that has received a patent from the patent office (and not by fraud. . .), and thus enjoys the presumption of validity that attaches to an issued patent, 35 U.S.C. § 282, is entitled to defend the patent's validity in court, to sue alleged infringers, and to settle with them, whatever its private doubts, unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it, if the suit went to judgment.

Id. at 992-93. Although *Asahi Glass* did not involve an exclusion-payment settlement, Judge Posner employed a similar approach to that of the Eleventh Circuit in *Valley Drug* in declining to independently assess the

likely validity of the patent unless it was almost certainly invalid or obtained by fraud.[10, 11]

The district court's approach in *Tamoxifen*

This district has also previously adjudicated the legality of a settlement of a patent litigation in which the validity of the patent was less than certain, without engaging in a *post hoc* analysis of the patent's validity. *See In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121 (E.D.N.Y. 2003) (Glasser, J.). In that case, the brand-name manufacturer, Zeneca, settled with the first generic challenger - coincidentally, Barr - after Barr had obtained a district court judgment, at that time on appeal, that the patent was invalid and unenforceable. *Id.* at 125. Under the settlement, Zeneca paid Barr $21 million and licensed Barr to sell tamoxifen manufactured by Zeneca for a royalty in exchange for Barr's withdrawal of its challenge to the validity to the patent and agreement not to market its generic version of tamoxifen until the patent expired. *Id.* Barr and Zeneca jointly moved the appeals court to dismiss the appeal as moot in light of the settlement and to vacate the judgment below, which motions were granted. *Id.* Three

10. Neither the Eleventh Circuit nor Judge Posner furnished any examples of or provide further guidance regarding patents that were so blatantly invalid.

11. It happens that Judge Posner did in fact decide the validity of the patent in a related patent infringement case that was decided prior to *Asahi Glass*. *See Asahi Glass*, 289 F. Supp. 2d at 992. In that case he found the patent to be valid. *Id.*

additional generic manufacturers subsequently challenged Zeneca's patent for tamoxifen, and the patent was upheld in each instance, despite an attempt by one of the challengers to invoke collateral estoppel based on Barr's earlier vacated district court judgment. *Id.* at 126-27.

The district court dismissed the subsequent antitrust action brought by consumers, third-party payors and consumer advocacy groups alleging that they were forced to pay higher prices for tamoxifen as a result of the Zeneca/Barr settlement agreement. The court reasoned: "The lack of competition was not the result of any anti-competitive conduct by Zeneca or Barr, but rather the result of the existence of the '516 patent and the decision by the patent holder to enforce it." *Id.* at 138. In reaching this conclusion, the court did not independently assess the probable validity of the patent, even in light of the earlier district court's finding of invalidity and unenforceability, although it did note the traditional *Walker Process*-type exceptions for patent antitrust liability where the patent is fraudulently procured or the infringement action was a sham. *Id.* at 136.

The Federal Trade Commission's approach in *Schering-Plough*

In a decision heavily relied on by plaintiffs for its holding that exclusion payments exceeding litigation costs up to $2 million are prohibited under the Federal Trade Commission Act, the FTC also "question[ed] the

utility of a rule that would give decisive weight to an after-the-fact inquiry into the merits of the patent issues in a settled case."[12] *In re Schering-Plough Corp*, No. 04-10688, 2003 WL 22989651 (FTC Dec. 8, 2003) ("*Schering-Plough I*"), *set aside and vacated*, *Schering-Plough Corp. v. Federal Trade Comm'n*, __ F.3d __ , 2005 WL 528439 (11th Cir. Mar. 8, 2005) ("*Schering-Plough II*").

The facts of that case involved two settlement agreements - one between Schering-Plough, the brand-name manufacturer of two extended-release microencapsulated potassium chloride products, K-Dur 20 and K-Dur 10, and Upsher, a generic manufacturer, and one between Schering-Plough and American Home Products ("AHp"), another generic manufacturer. *Id.* at *7. The Schering/Upsher agreement, entered on the eve of the parties' Hatch-Waxman patent infringement trial, called for Schering to make payments totaling $60 million to Upsher in exchange for, *inter alia*, Upsher's agreement not to enter the market with any generic version of K-Dur 20 for over four years. The Schering/AHP settlement, which also ended a Hatch-Waxman patent infringement trial, required Schering-Plough to make payments totaling $30 million in exchange for AHP's agreement not to market any generic version of K-Dur 20 for at least six years. *Id.* After rejecting Schering-Plough's argument that it had received any other consideration for its payments than Upsher's and

12. The ruling was recently set aside and vacated by the Eleventh Circuit on other grounds (*i.e.*, not on the issue of the propriety of *post hoc* evaluations of a patent's validity).

Appendix C

AHP's agreements to delay marketing (both agreements included ancillary licenses), the FTC condemned the agreements as anti-competitive, but not on the basis of a *post hoc* review of the patents' validity.

The FTC provided a pragmatic reason for its refusal to assess validity, which had not been previously articulated by courts considering the issue:

> An after-the-fact inquiry by the Commission into the merits of the underlying litigation is not only unlikely to be particularly helpful, but also likely to be unreliable. As a general matter, tribunals decide patent issues in the context of a true adversary proceeding, and their opinions are informed by the arguments of opposing counsel. Once a case settles, however, the interests of the formerly contending parties are aligned. A generic competitor that has agreed to delay its entry no longer has an incentive to attack vigorously the validity of the patent in issue or a claim of infringement.

Schering-Plough I, 2003 WL 22989651, at *19.[13]

13. Plaintiffs here have raised a similar argument, suggesting that Barr's attorneys had developed a particularly strong attack on the '444 Patent that no subsequent challenger was capable of replicating. Indir. Pls.' Mem. of Law in Opp'n to Bayer's Mot. for Partial Summ. J. on Count V ("Indir. Pls.' Count V Opp'n"), at 2-4; Indir. Pls.' Mem. of Law in Opp'n to Generic Defs.' Mot. for Summ. J. and Bayer's Mot. for Partial Summ. J. on Pls.' Claims Under the (Cont'd)

Appendix C

Although the Eleventh Circuit heavily criticized the FTC for other aspects of its decision, it had no quarrel with the FTC's rejection of a *post hoc* analysis of patent validity, as its own analysis took no account of the potential invalidity of the patent. *Schering-Plough II*, ____F.3d____, 2005 WL 528439.

This survey of the case law reveals that, with the possible exception of the Eleventh Circuit's instructions to the district court on remand in the *Valley Drug* case (*see* discussion *supra*), courts assessing the legality of patent settlement agreements have not engaged in a *post hoc* determination of the potential validity of the underlying patent (except in cases of *Walker Process* or sham litigation claims) when deciding whether an agreement concerning the patent violates antitrust law. These authorities are persuasive.

Above all, making the legality of a patent settlement agreement, on pain of treble damages, contingent on a later court's assessment of the patent's validity might chill patent settlements altogether. Moreover, as explained *infra*, such an approach would undermine the presumption of validity of patents in all cases, as it could not logically be limited to drug patents, and would work a revolution in patent law.

(Cont'd)

Sherman Act and Corresponding State Law Claims ("Indir. Pls.' Sherman Opp'n"), at 13. Barr's patent counsel are undoubtedly fine attorneys, but it strains credulity to maintain that only one competitor's well-funded legal team could construct such a compelling case against the patent.

In any event, although "the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into," *Valley Drug*, 344 F.3d at 1306, a *post hoc* assessment of the validity of the ciprofloxacin patent it would likely do plaintiffs little good. After all, the '444 Patent has withstood multiple subsequent challenges and its validity has been affirmed by the Federal Circuit.[14] At oral argument, plaintiffs asserted that the court should give little weight to these subsequent failed attacks because none of them raised what plaintiffs believe to be the most forceful attack on the '444 Patent - namely, inequitable conduct. Plaintiffs argue that this defense required extensive discovery and would take a long period of time to prepare and try, and that this explains why none of the subsequent challengers raised this issue.

But this argument is not very convincing in light of the fact that one of the challenges - Carlsbad's, on the ground of obviousness - also required extensive discovery and resulted in a nine-day bench trial. It is difficult to accept the notion that Carlsbad abandoned a stronger argument because it would have presumably required a greater effort, especially since Barr had already done most of the preparatory work on the inequitable conduct issue.

---

14. Indeed, there is something anomalous about the notion that plaintiffs could collect treble damages for settlement of a litigation involving a patent that has been subsequently upheld by the Federal Circuit. Even the FTC's decision in *Schering-Plough* outlawing exclusion payments provided for prospective relief only. *Schering-Plough I*, 2003 WL 22989651, at *43.

Plaintiffs further argue that the '444 Patent that emerged from reexamination in the PTO after Bayer's settlement with Barr was much changed from the '444 Patent that Barr had challenged, insinuating that the allegedly strong inequitable conduct defense that Barr had developed would be weaker, or possibly even unavailable, in the hands of challengers of the reexamined '444 Patent. Indir. Pls.' Count V Opp'n, at 3. This is clearly wrong, since the defense of inequitable conduct was available for all the '444 Patent's post-reexamination challengers. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1182 (Fed. Cir. 1995) (affirming a finding of inequitable conduct, notwithstanding that the withheld reference was later cited during reexamination and the claims were allowed to issue). Thus, the ability of the patent to withstand the subsequent challenges is persuasive, and that there is little likelihood that plaintiffs here would prevail in a *post hoc* attack on the patent.

In sum, it is inappropriate for an antitrust court, in determining the reasonableness of a patent settlement agreement, to conduct an after-the-fact inquiry into the validity of the underlying patent. Such an inquiry would undermine any certainty for patent litigants seeking to settle their disputes. In addition, exposing the parties to a patent settlement agreement to treble antitrust damages simply because the patent is later found to be invalid would overstep the bright-line rule adopted by the Supreme Court in *Walker Process*, first elaborated upon by Justice Harlan in his concurrence and relied

upon by the patent bar for the past forty years. *Walker Process*, 382 U.S. at 179-80, 86 S.Ct. at 351-52 (1965).[15]

ii. The effect of the possible invalidity of the patent on the legality of the Agreements

Having resolved that the validity of the '444 Patent should not be independently assessed, the next question that needs to be addressed is how the *possibility* that the patent is invalid should affect the legality of an exclusion payment. The heart of plaintiffs' argument is that there was at least a chance that the '444 Patent was invalid and, therefore, the Agreements violated antitrust law because the patent rights they enforce derive from a potentially invalid patent. They argue that the potential invalidity of the patent translates into a potential for open competition (and, hence, lower prices), and that the possibility of realizing such open competition was unfairly foreclosed by the Agreements.

Although plaintiffs do not attempt to litigate the validity of the '444 Patent in their motion for summary judgment, or in their opposition to defendants' motions for summary judgment, they do argue that the patent's potential invalidity should be taken into account when assessing whether the anti-competitive effects of the Agreements exceed the exclusionary scope of the

15. Indirect plaintiffs have added Count V to their complaint, alleging a state law *Walker-Process*-type claim, namely that Bayer obtained the '444 Patent through fraud and that its suit against Barr was a sham litigation. These allegations are discussed more fully in connection with Bayer's motion to dismiss, *see infra* Part 3.

patent. These arguments, plaintiffs assert, do not depend on an analysis of the '444 Patent's validity. In that regard, plaintiffs advance the reasoning of the FTC in *Schering-Plough*, now rejected by the Eleventh Circuit, and the views of several academics.

The starting point of the FTC's analysis whether the exclusion payments in that case were anti-competitive was to compare the amount of competition that occurred under the exclusion payment to "the amount of competition that was likely to occur had it not been for the payment. . . ." *Schering-Plough I*, 2003 WL 22989651, at *16. The FTC then examined and rejected Schering's defense that the restraint on trade due to the exclusion payment was ancillary to the legitimate settlement of a patent dispute, reasoning that the amount of the payment ($60 million) was too high to be "a reasonably necessary element of a settlement that is procompetitive overall." *Id.* at 21. The FTC also rejected as implausible Schering's separate justification for the payment, that it was in exchange for some licenses. *Id.* at 40. The FTC concluded that the payment was made in exchange for delayed entry, and was therefore an agreement that "unreasonably restrains commerce." *Id.*

Plaintiffs note that the FTC relied on the economic analysis advocated by Professor Carl Shapiro in his article *Antitrust Limits to Patent Settlements*, 34 Rand J. Econ. 391 (2003), *see* Dir. Pls.' Summ. J. App., Tab 16, in which he states that, like litigants to a patent infringement suit, consumers have an "expected" gain

from the patent challenge that equals their actual gains if the patent is invalidated, discounted by the probability of its being upheld. Dir. Pls.' Mem. at 14. The parties to the litigation, Professor Shapiro argues, should not be allowed to bargain away this assumed consumer surplus in reaching their settlement. Shapiro, 34 Rand J. of Econ. at 396 ("[A] patent settlement cannot lead to lower expected consumer surplus than would have arisen from ongoing litigation. Effectively, consumers have a 'property right' to the level of competition that would have prevailed, on average, had the two parties litigated the patent dispute to a resolution in the courts.").

This concept of a public property right in the outcome of private lawsuits does not translate well into the realities of litigation, and there is no support in the law for such a right. There is simply no legal basis for restricting the rights of patentees to choose their enforcement vehicle (*i.e.*, settlement versus litigation). Equally important, there is no duty to use patent-derived market power in a way that imposes the lowest monopoly rents on the consumer. *See, e.g., E. Bement & Sons*, 186 U.S. at 91, 22 S.Ct. at 755; *Studiengesellschaft Kohle*, 670 F.2d at 1127. Requiring parties to a lawsuit either to litigate or negotiate a settlement in the public interest, at the risk of treble damages is, as a practical matter, tantamount to establishing a rule requiring litigants "to continue to litigate when they would prefer to settle" and "to act as unwilling private attorneys general and to bear the various costs and risks of litigation." *Nestle Co., Inc. v. Chester's Market, Inc.*, 756 F.2d 280, 284 (2d Cir. 1985); *see also Times Mirror*

Magazines, Inc. v. Field & Stream Licenses Co., 103 F. Supp. 2d 711, 741 (S.D.N.Y. 2000) ("Insisting that a court review a settlement [of a trademark suit] to assure that no public confusion will result would make such agreements of little value to the parties. . . . Parties would sensibly conclude that they might better litigate the issue of confusion to conclusion rather than reach a settlement which might later be found to be unenforceable.") (quoting *T & T Mfg. Co. v. A.T. Cross Co.*, 449 F. Supp. 813, 827 (D.R.I.), *aff'd*, 587 F.2d 533 (1st Cir. 1978), *cert. denied*, 441 U.S. 908, 99 S.Ct. 2000, 60 L.Ed.2d 377 (1979)); Gen Defs. Opp. Mem. at 16 ("Plaintiffs' rule that any of these settlements can be challenged by a third party claiming 'property rights' in some litigation outcome would increase the costs of litigation and of settlement by imbuing the entire process with an additional layer of uncertainty. Litigants would fear third-party challenges to settlements based on unknowable conceptions of what 'consumer surplus' might have occurred had litigation continued."). Although plaintiffs would no doubt argue that litigation is to be preferred in these drug patent cases, as pointed out in *Cipro II*, there is no support for the view that Hatch-Waxman intended to thwart settlements. *Cipro II*, 261 F. Supp. 2d at 256.

Furthermore, even assuming some consumer surplus that the parties are bound to respect in settlement negotiations, such an interest would first have to be quantified. In seeking to calculate this consumer surplus, plaintiffs first couch their analysis in probabilistic terms, acknowledging this court's earlier

admonishment that antitrust liability cannot be predicated on the possible outcome of litigation. Dir. Pls.' Mem. at 12-23; *Cipro II*, 261 F. Supp. 2d at 202; *Schering-Plough I*, 2003 WL 22989651, at *16. In particular, plaintiffs argue that every patent has a chance of being held invalid, which should inure to the public's benefit. Dir. Pls.' Mem. at 12-23 (citing Shapiro, 34 Rand J. of Econ. at 395 ("[A] patent is best viewed as a *probabilistic* property right. What the patent grant actually gives the patent holder is the right to sue to prevent others from infringing the patent. Nothing in the patent grant guarantees that the patent will be declared valid, or that the defendant in the patent suit will be found to have infringed. ") (emphasis in original)).

To support this approach, plaintiffs resort to generalized statements about how patents fare in the courts. Dir. Pls.' Mem. at 18 ("Defendants themselves have admitted that, except in the rarest of cases, no patent stands a greater than 70% chance of being found to be valid."). This argument has some facial appeal, as it is common knowledge that many patents, once challenged, are ultimately held invalid and/or unenforceable. *See, e.g.*, Dir. Pls.' Summ. J. App., Tab 15 (John R. Allison and Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205 (1998) (showing that nearly half of all litigated patents are found to be invalid)).

Ultimately, however, this argument proves too much. To begin with the premise, as characterized by generic defendants, that every patent is "a little bit invalid,"

results in undermining the presumption of validity that Congress has afforded patents. 35 U.S.C. § 282 ("A patent shall be presumed valid."); *see* Generic Defs.' Mem. in Opp'n to Direct Purchaser Pls.' Mot. for Partial Summ. J., at 9. Moreover, this premise could have far-reaching effects on everyday patent transactions. *See Schering-Plough II*, __F.3d at __, 2005 WL 528439, at *8 ("Indeed, application of antitrust law to markets affected by the exclusionary statutes set forth in patent law cannot discount the rights of the patent holder.") (citing *Simpson v. Union Oil Co.*, 377 U.S. 13, 14, 84 S.Ct. 1051, 12 L.Ed.2d 98 (1964)). For example, whenever a patentee and accused infringer enter a settlement (usually a license agreement), the accused infringer always either explicitly or implicitly acknowledges the patent's validity, and in many cases must pay the patentee a royalty if it wishes to continue selling the infringing goods.

Although plaintiffs contend that entry with a license is preferable to no entry at all, unless the license is royalty-free, the royalty itself is a barrier to entry, anathema to unfettered competition and, depending on the royalty rate, may offer minimal benefit to the public. If the settlement with a payment to a generic is to be subject to antitrust liability, even though it does not exceed the scope of the patent, the next antitrust challenge to a patent settlement might well take place in the context of a license with royalty, a result that even Professor Shapiro would presumably disfavor. *See, e.g.*, Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. of Econ. at 395 ("[A] prohibition on settling

patent disputes cannot make sense: as noted earlier, virtually every patent license can be viewed as the settlement of a patent dispute, and settlements generally can provide many benefits not only to the settling parties but to consumers as well."). To open royalty-bearing patent license agreements to antitrust scrutiny simply because patents are often held invalid when tested in litigation would undermine the settled expectations of patentees and potential infringers/licensees across countless industries. *See In re Tamoxifen*, 277 F. Supp. 2d at 137 ("No antitrust injury can flow from the prices at which Zeneca licensed tamoxifen to Barr."); *see also Studiengesellschaft Kohle*, 670 F.2d at 1127.

Plaintiffs argue, as an alternative to the probabilistic method described above, that the potential invalidity of the patent can be inferred from the parties' behavior. Plaintiffs suggest that the settlement amount is evidence of the patent's fallibility because its value exceeds the litigation costs of fending off a challenge. Mem. of Dir. Pls. in Opp'n to Defs.' Mots. for Summ. J. at 45. Plaintiffs make the sensible argument that the higher the patentee's expectation of invalidity, the more it will be willing to pay a generic challenger to concede validity and stay out of the market. Thus, the very amount of the exclusion payment is evidence of the probable invalidity of the patent. Indeed, Bayer's own documents bear this theory out: a presentation slide prepared by Bayer's chief negotiator of the Bayer/Barr settlement contains the title, "The maximum settlement amount we should consider paying increases as the risk of losing

increases." Dir. Pls.' Summ. J. App., Tab 47B, at BCP-P-0001668A-004. It is worth mentioning that the presentation slide in question includes a graph plotting Bayer's perceived risk of losing against various dollar amounts and that the amount Bayer ultimately paid Barr (approximately $398 million) is at the 20-25 percent risk-of-loss mark.[16]

However, although direct plaintiffs contend that the amount of the exclusion payment in this case - $398 million - corresponds to a perceived chance of losing of about 50 percent, in absolute numbers Bayer's perceived chance of losing would appear to be much lower. How direct plaintiffs calculated this number is difficult to fathom,[17] especially since they cite Professor Hovenkamp's explanation of expected gains and losses in analyzing the anti-competitive effects of exclusion payments, who states: "[I]f the patentee has a 25% chance of losing, it is willing to pay up to 25% of the value of its monopoly to exclude its competitors without a trial." Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1759 (2003). Applying this model to Bayer's situation - plaintiffs submit that Bayer stood to lose more than $1.5 billion in profits if the '444 Patent was

16. In fact, once the $398 million is converted to the then-net present value, the corresponding perceived risk of losing is even lower.

17. As their expert candidly admits, "[t] he formulae underlying these calculations are complex." Dir. Pls.' Summ. J. App., Tab 33 (Expert Rep. of Keith B. Leffler, Ph.D., at 34 n. 85).

invalidated - reveals that Bayer's payment of $398 million translates to a perceived chance of losing of 26.5 percent. Of course, Bayer's payment to Barr was likely also constrained by the maximum amount Bayer expected Barr to make if it won the lawsuit, but applying a straight "expectation" economic analysis to these facts would indicate that Bayer was relatively confident of its chances of winning at trial.[18]

Plaintiffs' point is well-taken that the greater the chance a court would hold the patent invalid, the higher the likelihood that the patentee will seek to salvage a patent by settling with an exclusion payment. If courts do not discount the exclusionary power of the patent by the probability of the patent's being held invalid, then

18. This absolute numbers "expectation" model is interesting, particularly in that it happens to line up with the graph on Bayer's presentation slide, but there is no reason to rely upon it for an analysis of the legality of Bayer's payment to Barr. Moreover, this model may be overly simplistic, in that it does not account for other factors underlying the parties' negotiations, such as the possibility that subsequent challengers might enter the market for generic Cipro. In addition, both the indirect plaintiffs and the generic defendants asserted at oral argument that such a model should not be used in assessing the legality of the payment in this case. Indirect plaintiffs argue that a better measure of Bayer's perceived chances of winning the litigation against Barr could be extrapolated from a comparison of the actual payment to Barr's anticipated profit had it won the litigation. Generic defendants, on the other hand, accept that the expectation model could be used to approximate Bayer's perceived chances of success, but assert that the legality of the payment depends not on Bayer's subjective perception of its chances, but rather only on whether the patent litigation was a sham.

the patents most likely to be the subject of exclusion payments would be precisely those patents that have the most questionable validity. This concern, on its face, is quite powerful. But the answer to this concern lies in the fact that, while the strategy of paying off a generic company to drop its patent challenge would work to exclude that particular competitor from the market, it would have no effect on other challengers of the patent, whose incentive to mount a challenge would also grow commensurately with the chance that the patent would be held invalid. *See, e.g.*, Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. Rev. 11, 25 (2004) ("In a world in which there are numerous firms willing and able to enter the market, an exit payment to one particular infringement defendant need not have significant anticompetitive effects. If there is good reason for believing the patent invalid others will try the same thing."). Moreover, it is unlikely that the holder of a weak patent could stave off all possible challengers with exclusion payments because the economics simply would not justify it. *Cf. id.* at 25 n.54 (noting "ample history of litigation among large numbers of rivals being settled with a comprehensive licensing agreement," but acknowledging that those settlements "typically did not involve exit payments, but rather cross-licenses"). It could, therefore, be expected that the market would correct for any bolstering of flagrantly invalid patents by way of exclusion payments.[19]

19. A similar argument could be constructed for situations, unlike the one here, where infringement is the dominant issue in the underlying patent litigation. If the scope of the claims is in dispute, but arguably narrow enough that not every bioequivalent

(Cont'd)

See, e.g., Andrx Pharma., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 814 (D.C. Cir. 2001) ("Antitrust law looks at entry into the market as one mechanism to limit and deter exploitation of market power by those who may temporarily possess it. 'Existing firms know that if they collude or exercise market power to charge supracompetitive prices, entry by firms currently not competing in the market becomes likely, thereby increasing the pressure on them to act competitively.'") (quoting *FTC v. H.J. Heinz Co.*, 246 F.3d 708, 717 n.13 (D.C. Cir. 2001)).

Plaintiffs counter that such a market correction would have no impact on the injury to the market in the period before a subsequent challenger successfully invalidates the patent. But that is true in the case of all patents, not just pharmaceutical patents. Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent. *Cf. Schering- Plough II*, __F.3d at__ , 2005 WL 528439, at *8 ("By virtue of its '743 patent, Schering obtained the legal right to exclude Upsher and ESI from the market until they proved either that the '743 patent was invalid or that their products . . . did not infringe Schering's

(Cont'd)
generic drug would infringe the patent, it could be expected that additional generic challengers would be spurred to design around the patent and file their own ANDA IVs based on non-infringement.

patent."). More significantly, this type of delay is entirely within the control of the would-be subsequent challengers, who alone decide when they will challenge the patent by filing an ANDA IV.[20]

Plaintiffs further argue that the very fact that Bayer made an exclusion payment evidences the anti-competitive nature of the Agreements because a brand-name manufacturer's exclusion payments "eliminate its expected losses under litigation - and therefore eliminate consumers' expected gains under litigation . . . ." Dir Pls.' Mem. at 17. Plaintiffs again point to the FTC's decision:

> If there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.

---

20. Barr filed its ANDA IV on the first day it was permitted to do so under 21 U.S.C. § 355 (j) (5) (D) (ii). *See Cipro II*, 261 F. Supp. 2d at 194. There was no legal bar to other generics filing ANOA IVs that same day or any day thereafter, although pragmatic and economic considerations may have influenced their decision to wait at least until Barr's challenge had concluded before launching their own attacks on the '444 Patent. This is because if Barr were successful, the marketing approval for other generics would be withheld until Barr's 180-day exclusivity period expired.

Schering-Plough I, 2003 WL 22989651, at *16. The problem with this argument is that, due to the disparity between the brand-name manufacturer's and generic challenger's expected profits, there might not be any date that represents a reasonable litigation compromise for early (pre-patent expiration) entry by the generic challenger. The FTC acknowledges that "[t]he anticipated profits of the patent holder in the absence of generic competition are greater than the sum of its profits and the profits of the generic entrant when the two compete." *Id.* Thus, for each day of early (royalty-free) entry by the generic challenger, the brand-name manufacturer will lose many times more in expected profits than the generic challenger will gain. This is, of course, the reason why brand-name manufacturers make exclusion payments rather than granting a license. There simply is no otherwise reasonable litigation compromise.

Moreover, plaintiffs' assertion that Bayer's payment to Barr is anti-competitive because, without it, Bayer and Barr would have agreed on an earlier entry date for Barr or would have otherwise fashioned a more pro-competitive agreement must also fail. This assertion ignores the fact that, if defendants were within their rights (more specifically, the patent right) in reaching the settlement they did, consumers have no right to second-guess whether some different agreement would have been more palatable. *See, e.g., Verizon Comm'n Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415-16, 124 S.Ct. 872, 883, 157 L.Ed.2d 823 (2004) ("The Sherman Act . . . does not give judges carte

blanche to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition."). In sum, Bayer and Barr cannot be penalized just because plaintiffs can imagine a more pro-competitive settlement, if the agreement they did reach does not adversely affect competition beyond the scope of the '444 Patent.[21]

Finally, plaintiffs argue that Congress granted only a rebuttable presumption of validity, not a conclusive

---

21. Candor requires that I recognize that this conclusion is, to some extent, inconsistent with the view expressed in *Cipro I* regarding the motions to remand, where the opinion stated:

> A review of [plaintiffs'] allegations makes plain that plaintiffs have asserted at least one theory by which they may establish state antitrust violations without resorting to a determination of patent law. Plaintiffs' complaints allege there would have been generic competition in the market for ciprofloxacin prior to the expiration of Bayer's patent if Bayer had not reached an unreasonably anticompetitive agreement with Barr, HMR, and Rugby . . . [Plaintiffs] asserted that, as a matter of fact, Bayer would have authorized Barr to distribute ciprofloxacin by granting Barr a license, or by other means, had Barr not agreed to drop its challenge to the validity of the '444 patent in exchange for large cash payments.

Cipro I at 748.

Upon further reflection, I have concluded that patent law imposes no such restriction against cash payments by a patent holder, and, accordingly, antitrust law does not impose such a restriction.

presumption, and that by making a payment, Bayer is buying that which Congress declined to grant. This argument was explicitly rejected by the Eleventh Circuit in *Valley Drug*:

> We cannot conclude that the exclusionary effects of the Agreements not to enter the market were necessarily greater than the exclusionary effects of the '207 patent merely because Abbott paid Geneva and Zenith in return for their respective agreements. If Abbott had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit. The failure to produce the competing terazosin drug, rather than the payment of money, is the exclusionary effect, and litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement.

Valley Drug, 344 F.3d at 1309.

The FTC held that the Schering-Plough exclusion-payment patent settlements violated Section 5 of the Federal Trade Commission Act, *Schering-Plough I*, 2003 WL 22989651, at *43, but specifically exempted from antitrust scrutiny settlements involving only an early entry date. *Id.* at 19 ("Under the standard we adopt here, if the parties simply compromise on the entry date, standing alone, they do not need to worry about a later

antitrust attack."). The difficulty with this approach is that it is not clear that consumers would benefit more from such an arrangement than from an exclusion-payment settlement like the one here. Presumably, the parties to a Hatch-Waxman patent litigation could settle on an early entry date with a license calibrated to achieve a similar financial result to the parties as an exclusion payment. In response to questions on this point at oral argument, indirect plaintiffs and generic defendants agreed that some sort of license, such as an exclusive license for a limited geographic area, "theoretically" could have been negotiated that would, as between the parties, approximate the effect of an exclusion payment. Indir. Pls.' Resp. to the Court's Questions, at 3; Gen. Defs.' Resp. to the Court's Feb. 22, 2005 Questions, at 4. Bayer and Barr, however, focused as they were on defeating plaintiffs' theory that, absent the payment, Bayer and Barr would have agreed on an earlier entry date, were reluctant to concede the point. As Professor Hovenkamp points out,

> In a perfectly functioning market without transaction costs, a monopoly producer would be indifferent between producing everything itself and simply 'licensing' another to make part of its production. The license fee would be the monopoly markup, output would remain at the monopoly level as it would in any perfect cartel agreement, and the monopolist would earn the same profits, although part of them would be paid as license fees rather than as markup on goods that it

> produced. If all parties were completely certain that a patent was valid and infringed, a patentee would have precisely the same set of incentives. It would either produce all output under the patent itself, or else it would license some output to a rival, earning the monopoly profits as royalties. Assuming zero transaction costs, however, a firm in that position would have no incentive whatsoever to pay another firm to stay out of the market. It could exclude without paying anything at all.

Hovenkamp, 87 Minn. L. Rev. at 1750-51.

Assuming the soundness of Professor Hovenkamp's analysis (and it is hard to see how it can be contested), if the monopolist's profit margins are extraordinarily high, the royalty on an early-entry license could be so high that the generic company's prices would be no lower than the brand-name manufacturer's. In this case, given Bayer's projected price drop of 95 percent a year in the future, it is reasonable to infer that Bayer's profit margin for Cipro was in excess of 95 percent.[22] In fact, plaintiffs concede that the terms of Bayer's six-month license to Barr called for an 85 percent royalty, but they complain that the license did not benefit consumers

22. Indirect plaintiffs also allege in their pleadings that Bayer maintained an exceptional profit margin for Cipro: "Bayer's 1999 United States gross sales of Cipro were approximately $1.04 billion and its net sales (or profits) were in excess of $920 million." Indir. Pls.' Second Am. Consol. Class Action Compl. ¶ 70.

because the royalty was so high. Indir. Pls.' Sherman Opp'n, at 26. Indeed, indirect plaintiffs argue that a drug can only be considered "generic" if it is priced at least at a ten percent discount to its branded counterpart at the end-payer level, a standard that was not met by Barr's selling price under the six-month license from Barr, because the 85 percent royalty was paid at the wholesale, not retail, level. Thus, outlawing exclusion payment settlements in favor of early-entry licenses would not necessarily result in a public benefit or satisfy plaintiffs, unless royalty rates are also constrained. Such constraints on patent holders are, of course, impermissible. *See, e.g., E. Bement & Sons*, 186 U.S. at 91, 22 S.Ct. at 755 ("[T]he general rule is absolute freedom in the use or sale of rights under the patent laws of the United States.... The fact that the conditions in the contracts [for patent licenses] keep up the monopoly or fix prices does not render them illegal."); *Studiengesellschaft Kohle*, 670 F.2d at 1127 ("A patentee has the right to exclude others from profiting from the patented invention. This includes the right to suppress the invention while continuing to prevent all others from using it, to license others, or to refuse to license, and to charge such royalty as the leverage of the patent monopoly permits.") (citations omitted).

And even if royalty rates were suppressed so as to preserve some consumer benefit, at some point the interests of the patent holder and the generic would diverge so that settlement would be impossible and continued litigation the only viable course. While plaintiffs may view this as a desirable outcome, as noted,

the Eleventh Circuit vacated and set aside the FTC's opinion in *Schering-Plough* as inconsistent with the Eleventh Circuit's holding in *Valley Drug* that "[s]imply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law," unless the "exclusionary effects of the agreement" exceed the "scope of the patent's protection." *Schering-Plough*, __F.3d at__ , 2005 WL 528439, at *17.

A significant issue before the FTC was Schering's affirmative defense that the agreements to delay entry were ancillary to the legitimate settlement of a patent dispute. *Schering-Plough I*, 2003 WL 22989651, at *9, 20. Before measuring the anti-competitive impact of the agreements against the scope of the patent, the Eleventh Circuit reviewed the FTC's determination that Schering's payments to the generic companies were not *bona fide* royalty payments under the licenses Schering obtained from the generics, noting that "[t]he FTC concedes that its position fails if it cannot prove a direct causal link between the payments and the delay [in the generics entering the market]." *Id.*, __F.3d at__ , 2005 WL 528439, at *10. After rejecting the FTC's determination as "not supported by law or logic," the Eleventh Circuit then characterized the aspect of the agreements dealing with the delay in generic marketing as "ancillary restraints" which are "secondary and collateral to an independent and legitimate transaction." *Id.*, F.3d at 2005 WL 528439, at *14. Noting that such ancillary restraints "are generally permitted if they are reasonably necessary toward the contract's objective of

utility and efficiency," the Eleventh Circuit found that the delay provisions were appropriately narrow, as they reached only products that were covered by Schering's patent. *Id.*

Plaintiffs point to the Eleventh Circuit's lengthy discussion of whether the payments were *bona fide* royalty payments as a disavowal of a rule that any payment from the patent holder for a competitor's exclusion that is within the scope of the patent is exempt from antitrust scrutiny. Letter from Steve D. Shadowen dated 3/15/2005, at 2-3. Instead, plaintiffs view that discussion as expressing agreement with plaintiffs' position that such payments in exchange for delay do in fact exceed the scope of the patent. *Id.* A more plausible explanation for the Eleventh Circuit's in-depth treatment of the bona fide royalty question is that the discussion framed the issue of whether the delay aspects of the agreements were ancillary restraints or not. Indeed, the Eleventh Circuit's endorsement of a rule permitting exclusion payments that do not exceed the scope of the patent could hardly be clearer:

> We have said before, and we say it again, that the size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy. Due to the assymetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement. An exception cannot lie . . . when the issue turns on validity

> (*Valley Drug*) as opposed to infringement (the Schering agreements). The effect is the same: a generic's entry into the market is delayed. What we must focus on is the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection. Here, we find that the agreements fell well within the protections of the '743 patent, and were therefore not illegal.

Schering-Plough II, __F.3d at__ , 2005 WL 528349, at *17 (citations and internal quotation marks omitted).

Plaintiffs also argue that the Eleventh Circuit's concluding admonition that there is a need "to evaluate the strength of the patent," *Schering-Plough II*, __F.3d at __, 2005 WL 528349, at *17, bolsters plaintiffs' argument that the potential invalidity of the '444 Patent should be taken into account when measuring the exclusionary scope of the patent. Letter from Joseph Lipofsky dated 3/14/2005, at 1-2. In the context of both the opinion as a whole and the controlling precedent of *Valley Drug*, this admonition is more fairly read as requiring an evaluation of the scope of the patent's claims, and not a *post hoc* analysis of the patent's validity, an approach which, as discussed *supra* at Part (1) (b) (i), has not been endorsed by any court other than the *Valley Drug* district court on remand.

To summarize, it would be inappropriate to engage in an after-the-fact analysis of the patent's likely

validity.[23] Nor is it appropriate to discount the exclusionary power of the patent by any probability that the patent would have been found invalid. Moreover, the FTC's now-vacated rule that exclusion payments beyond litigation costs are always illegal should be rejected because it ignores the justified needs of the patent holder in the face of the risks of litigation, especially in an arena where it is well-known that courts are far from error-free.[24] The test for determining the validity of the so-called reverse or exclusion or exit

---

23. Of course, as previously discussed, such an inquiry would hardly redound to plaintiffs' benefit, given that the '444 Patent has already been upheld by the Federal Circuit once, that three other attacks have failed and that only a speculative attack is proposed by the plaintiffs here. *See supra* Part 1(b) (i).

24. At least two commentators have suggested that, "[f] or purposes of antitrust analysis, there are and can be no 'wrong' decisions reached by courts in patent litigation . . . [because] [t]he substantive rights granted by Congress to patent holders are those rights . . . which a federal court determines, through congressionally prescribed process, that the patent holder possesses. Because there are no 'wrong' results generated by the patent litigation process, the patent holder improperly enlarges the innovation reward granted to him by Congress when he buys 'insurance' - in the form of exclusion of a competitor – against a 'wrong' result in the patent litigation." Keith B. Leffler and Cristofer I. Leffler, *Want to Pay a Competitor to Exit the Market? Settle a Patent Infringement Case*, 2 ABA Economics Committee Newsletter 26 (Spring 2002). The fallacy of this argument is that it leads to the inevitable conclusion that it is always improper for a patentee to insure against an unfavorable result by paying for a competitor's exclusion. All hedging by patentees - that is, all patent settlements - are now suspect.

payment and the only question remaining is whether the Agreements constrained competition beyond the scope of the patent claims. Here, the only serious argument plaintiffs have raised in that regard is possible manipulation of the 180-day exclusivity period by Barr. However, the theory was fully briefed and disposed of in the *Cipro II* decision and need not be decided anew here. *Cipro II*, 261 F. Supp. 2d at 243-47. In short, Barr's amendment of its ANDA IV to an ANDA III cleared the way for subsequent generic companies to mount challenges to the '444 Patent, an eventuality that was borne out. At least four generic companies filed ANDA IVs after Bayer and Barr entered the Agreements, so it cannot be reasonably argued that the Agreements created a bottleneck to future generic challenges.

Plaintiffs complain that they have been doubly harmed by the Agreements: first by the exclusion of Barr from the market, and second by Bayer's passing on the cost of the settlement payment in the form of increased prices for Cipro. However, if the Agreements themselves do not exceed the exclusionary power of the '444 Patent, any increased prices resulting from the Agreements are the result of the monopoly inherent in the patent. Indeed, "an exclusion of competitors and charging of supracompetitive prices are at the core of the patentee's rights, and are legitimate rewards of the patent monopoly." *Studiengesellschaft Kohle*, 670 F.2d at 1128 (citing *Brulotte v. Thys Co.*, 379 U.S. 29, 33, 85 S-.Ct. 176, 179, 13 L.Ed.2d 99 (1964) (dictum); *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 136, 89 S.Ct. 1562, 1583, 23 L.Ed.2d 129 (1969)). Of course,

market forces may impose some limits on the prices a patentee can charge. At some point, additional competitors will be spurred to either challenge the patent or design around it, or consumers will find a more affordable (although perhaps less desirable) alternative. *See, e.g., Andrx v. Biovail*, 256 F.3d at 814.

To conclude, in the absence of any evidence that the Agreements created a bottleneck on challenges to the '444 Patent, or that they otherwise restrained competition beyond the scope of the claims of the '444 Patent, the Agreements have not had any anti-competitive effects on the market for ciprofloxacin beyond that which are permitted under the '444 Patent. The fact that Bayer paid what in absolute numbers is a handsome sum to Barr to settle its lawsuit does not necessarily reflect a lack of confidence in the '444 Patent, but rather the economic realities of what was at risk. There is simply no precedent for plaintiffs' argument that the parties to a settlement are required to preserve the public's interest in lower prices. Such a rule would only result in parties being less likely to reach settlements, aside from undermining well-settled principles of patent law. Finally, to even attempt to quantify the public's interest in a patent settlement between private parties would require devaluing patents across the board, a result that would contravene the presumption of validity afforded by Congress and impact the very way patent licenses are handled in countless daily transactions.

Because plaintiffs have not shown that the Agreements had anti-competitive effects beyond the

scope of the '444 Patent, it is not necessary to address the second and third steps of the rule-of-reason analysis - whether defendants can establish the "pro-competitive redeeming virtues" of the Agreements, and whether plaintiffs can "show that the same pro-competitive effect could be achieved through an alternative means that is less restrictive of competition." *K.M.B. Warehouse*, 61 F.3d at 127.

(2)

Consumer Antitrust Standing

As the law now stands, the validity of a patent may be challenged only by an alleged infringer as an affirmative defense or counterclaim to an infringement action brought by the patentee, or by a declaratory judgment plaintiff, who must show

> (1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken by the declaratory judgment plaintiff with the intent to conduct such activity.

Teva Pharma. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1330 (Fed. Cir. 2005). Therefore, at present, non-infringing consumers of patented products who may feel

that they are being charged supracompetitive prices by the patentee have no cause of action to invalidate the patent.

It is also apparent that Congress did not intend to change the standing requirements for actions to invalidate patents when it passed, and still more clearly when it later amended, the Hatch-Waxman Amendments in 2003. *See* Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, entitled "Access to Affordable Pharmaceuticals" ("Medicare Amendments"). Indeed, in the Medicare Amendments, which were passed on December B, 2003, after the issues revolving around exclusion-payment and other settlements between brand-name manufacturers and generics had already surfaced, Congress provided for explicit forfeiture of the 180-day exclusivity period that would otherwise be enjoyed by the first filer of an ANDA IV if the first filer settles its suit with the brand-name manufacturer, but only if the Federal Trade Commission or the Attorney General obtains a final decision from the Federal Trade Commission or a court that the agreement between the first filer and the brand-name manufacturer has violated the antitrust law. *See* 21 U.S.C. 355(j) (5) (D) (i) (V) (Supp. 2004).[25] Notably,

25. The subsection reads

> **(V) Agreement with another applicant, the listed drug application holder, or a patent owner**
>
> The first applicant [forfeits its 180-day exclusivity period if it] enters into an agreement with another

(Cont'd)

Appendix C

Congress made no provision for loosening the standing requirements for challenging patents or even for forfeiture of the 180-day exclusivity period where the antitrust complaint is brought by consumers.

Given that consumers are often subjected to monopoly prices for invalid patents, it is tempting to suggest that, as a policy matter, a rule should be fashioned giving consumers of drugs - and perhaps patented goods generally - the right to challenge the validity of patents. In other words, plaintiffs should be afforded the opportunity to challenge the exclusion-payment scheme at issue here - and licensing arrangements as well - by folding in a predicate challenge to the underlying patent itself. Under the proposed rule, the consumers would have to show by clear and convincing evidence - as accused infringers must - that the subject patent was invalid. This proposal would have

---

(Cont'd)

> applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2) (A) (vii) (IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of Title 15, except that the term includes section 45 of Title 15 to the extent that that section applies to unfair methods of competition).

the effect of allowing non-infringing consumers of a patented product to seek to invalidate the patent in order to allow price-reducing competitors to enter the market. The desirability of such a change is a complex issue which is not within the competence of judges. A thorough examination of the consequences of such a change would have to be made. For example, would such a change negatively impact the willingness of drug manufacturers to invest in research and development? Should consumers be permitted to recover punitive damages for the overcharges they have suffered? As Justice Harlan noted, patents are often set aside for any number of technical reasons. *Walker Process*, 382 U.S. at 179-80, 86 S.Ct. at 351-52. Perhaps permitting only declaratory relief, together with attorneys' fees, would solve the problem of unduly punishing those who in good faith sought patents that ultimately were shown to be invalid. Another possible alternative is to limit the consumer recovery to the amount of the monopolistic overcharges. These questions lead to the inevitable conclusion that such a change in public policy should be made by Congress, and not by the courts.

(3)

Bayer's Motion to Dismiss Count V of Indirect Plaintiffs' New Complaint

Recognizing that the ultimate vindication of the '444 Patent might immunize the Agreements from antitrust scrutiny under the rule of reason, indirect plaintiffs amended their complaint to add charges that would strip

Bayer of its patent immunity. Indir. Ps.' Mem. of Law in Opp'n to Bayer's Mot. for Partial Summ. J. on Count V, at 1. Six months after summary judgment motions were decided in *Cipro II*, indirect plaintiffs moved to amend their complaint to add claims that Bayer violated state antitrust and/or consumer protection laws by virtue of alleged inequitable conduct before the PTO in procuring the '444 Patent and alleged sham litigation in enforcing the '444 Patent against Barr. Indir. PIs.' Second Am. Consolo Class Action Compl., ¶¶ 296-308. The substance of this new count of the complaint, Count V, is that Bayer made a series of misrepresentations to the PTO in order to secure issuance of the '444 Patent, and then, with knowledge that the patent was invalid and had been fraudulently procured, asserted the patent against Barr even though no reasonable litigant in Bayer's position "at the time of its settlement with Barr" could have expected to win the litigation. Indir. PIs.' Second Am. Consolo Class Action Compl., ¶ 305. Bayer moves to dismiss Count V on two threshold grounds: that it is preempted by federal patent law and barred by the statute of limitations.

Ordinarily, antitrust claims premised on the enforcement of a fraudulently procured patent are brought by an accused infringer as a counterclaim to the original charge of infringement. *See, e.g.*, *Nobelpharma*, 141 F.3d at 1067 ("[A]n antitrust claim premised on stripping a patentee of its immunity from the antitrust laws is typically raised as a counterclaim by a defendant in a patent infringement suit.") Indirect plaintiffs' claims are unusual, both because they are

brought by indirect purchasers of the patented item and because they are asserted under state law. Whatever the reasons for indirect plaintiffs bringing *Walker Process* and sham litigation claims under state law, those claims are preempted by federal patent law and must, therefore, be dismissed.

28 U.S.C. § 1338(a) grants federal district courts exclusive jurisdiction over "any civil action arising under any Act of Congress relating to patents . . . ." Thus, if indirect plaintiffs' state law *Walker Process* and sham litigation claims "arise under" patent law, they may only be heard in federal court.[26] The Supreme Court elucidated what it means for a claim to "arise under" patent law in *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 809-11, 108 S.Ct. 2166, 100 L.Ed.2d 811 (1988). Under the well-pleaded complaint rule, plaintiffs' claim must be judged solely on the face of the complaint, without reference to any anticipated defenses; unless patent law is necessary to each and every theory under the claim, § 1338(a) jurisdiction will not be invoked. *Id.*

Here, indirect plaintiffs' Count V rests entirely on patent law. If indirect plaintiffs cannot prove that Bayer

---

26. Although the fact that a state law cause of action may only be heard in federal court does not necessarily mean that it is preempted by federal law, *see Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1334 (Fed. Cir. 1998), *overruled on other grounds by Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1358-59 (Fed. Cir. 1999), the inquiries are closely related and in certain circumstances do overlap.

intentionally withheld or misrepresented material information to the PTO during prosecution of the '444 Patent, their *Walker Process* and sham litigation claims cannot survive. Specifically, "[a] finding of *Walker Process* fraud requires higher threshold showings of both intent and materiality than does a finding of inequitable conduct. . . . [and] must be based on independent and clear evidence of deceptive intent together with a clear showing of reliance, *i.e.*, that the patent would not have issued but for the misrepresentation or omission." *Nobelpharma*, 141 F.3d at 1070-71. There is simply no theory for proving a *Walker Process* antitrust violation in this case that would not require a showing of misconduct before the PTO. Furthermore, the Federal Circuit has held that "whether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from the antitrust laws is to be decided as a question of Federal Circuit law." *Id.* at 1068 (*en banc* in relevant part). And while sham litigation could theoretically be shown by assertion of a patent known to be valid but not infringed, such a theory is not available in this case, where Barr admitted infringement, not just as part of the post-settlement consent judgment, but in the July 25, 1996 Stipulation and Order, entered long before the Agreements were ever negotiated. *See* Bayer Sherman Act App., Ex. 5 (Stipulation and Order (Barr's stipulation that it infringed the '444 Patent)). Indeed, Barr never contested infringement of the '444 Patent, even in its December 6, 1991 Paragraph IV detailed statement which triggered the Bayer/Barr patent litigation. Bayer Sherman Act App., Ex. 2.

Appendix C

The fact that indirect plaintiffs' Count V not only arises out of patent law, but rests entirely on patent law, leads to two conclusions. First, jurisdiction over Count V lies exclusively in federal court. 28 U.S.C. § 1338(a); *Christianson*, 486 U.S. at 809-11; *cf. Cipro I*, 166 F. Supp. 2d at 750-51 (holding that remand was appropriate where plaintiffs had "pleaded at least one theory under which their claims for relief may be resolved without determining the validity of Bayer's patent"); *but see Williams v. Del Monte Fresh Produce Co.*, 325 F. Supp. 2d 855, 858-60 (M.D. Tenn. 2004) (remanding to state court state law claims predicated on fraudulent procurement and enforcement of a patent, where patentee admitted invalidity of patent, thus obviating the need for the state court to adjudicate the federal question). Second, federal patent law preempts any state antitrust cause of action premised on Bayer's alleged bad faith conduct before the PTO because Count V does not allege any conduct other than conduct before the PTO. In other words, the state law remedies invoked by indirect plaintiffs are directed to allegedly tortious conduct before the PTO, not tortious conduct in the marketplace. *Cf. Hunter Douglas*, 153 F.3d at 1334; *Dow Chem. Co. v. Exxon Corp.*, 139 F.3d 1470, 1477 (Fed. Cir. 1998).

Indirect plaintiffs' Count V allegations parallel the abuse of process counterclaim brought in *Abbott Labs. v. Brennan*, 952 F.2d 1346 (Fed. Cir. 1992). There, the Board of Patent Appeals and Interferences awarded priority of invention in an interference proceeding to Brennan, even though Abbott had first conceived and

reduced the invention to practice because Abbott's attorney had backdated a request for extension of time and falsely averred that the request had been timely made. *Id.* at 1348. Abbott brought a civil action in district court seeking to set aside the award of priority to Brennan, and Brennan counterclaimed for, *inter alia*, the state law tort of abuse of process. The Federal Circuit reversed the judgment of abuse of) process, concluding "that the federal administrative process of examining and issuing patents, including proceedings before the PTO's boards, is not subject to collateral review in terms of the common law tort of abuse of process." *Id.* at 1357. The court reasoned that "[a]n additional state action would be an inappropriate collateral intrusion on the regulatory procedures of the PTO, 'under the guise of a complaint sounding in tort,' and is contrary to Congress' preemptive regulation in the area of patent law." *Id.* (quoting *Gilbert v. Ben-Asher*, 900 F. 2d 1407, 1411 (9th Cir. 1990)).

The allegations of Count V differ from the state law claim for unfair competition that was not preempted by federal law in *Dow*. There, Dow alleged that Exxon had threatened to sue actual and prospective Dow customers for patent infringement, even though Exxon allegedly had no good-faith belief that Dow infringed the patent when Exxon made the threats and had allegedly obtained the patent by inequitable conduct. *Dow*, 139 F.3d at 1472. The court held that the claim was not preempted because the tort claim was "not premised upon bad faith misconduct in the PTO, but rather [was] premised upon bad faith misconduct in the

marketplace." *Id.* at 1477. The marketplace misconduct in Dow was Exxon's threats to Dow's customers, not activity that occurred before the PTO or in the context of a litigation. *Id.* at 1472. Indirect plaintiffs' Count V does not allege any malfeasance in the marketplace such as threats to Barr or its customers, but instead rests entirely upon actions that occurred before the PTO. Because the allegations of Count V are coextensive with patent law, they are preempted by patent law. *See, e.g., Semiconductor Energy Lab. Co., Ltd. v. Samsung Elecs. Co. Ltd.*, 204 F.3d 1368, 1382 (Fed. Cir. 2000) (affirming dismissal of state RICO counterclaims that "occupy a field identical in scope with the inequitable conduct defense," and noting that "[a]n additional state cause of action predicated so squarely on the acts of inequitable conduct would be 'contrary to Congress' preemptive regulation in the area of patent law.'") (quoting *Abbott*, 952 F.2d at 1357).[27]

---

27. Indirect plaintiffs point to a number of cases in which state law causes of action predicated on bad faith procurement of patents have been allowed to go forward. Those cases do not alter the analysis, as none of them addresses preemption of state law *Walker Process* or sham litigation claims. For example, *In re Relafen Antitrust Litig.*, 221 F.R.D. 260 (D. Mass. 2004), deals with class certification issues, and makes only passing reference to one allegation that the defendants "entered the market under the banner of a patent procured by fraud." *Id.* at 266. The court's analysis was limited to a determination of whether the requirements of Rule 23 were met, and it did not consider the merits of the case. *Id.* at 265. In subsequent opinions, the *Relafen* court clarified that the indirect plaintiffs in that case were pursuing their *Walker Process* claims as assignees of the rights of several national wholesalers (*i.e.*,

(Cont'd)

Appendix C

The only conduct not directly referable to the PTO that indirect plaintiffs point to as an instance of marketplace "maintenance" of the '444 Patent is Bayer's compulsory listing of the '444 Patent in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," or the "Orange Book," as required under 21 U.S.C. § 355 (b) (1). Indir. Pls.' Second Am. Consolo Class Action Compl., ¶ 243; Indir. Pls.' Responses to the Court's Questions for Oral

---

(Cont'd)

direct purchasers), and their claims were therefore not barred by *Illinois Brick*. *See In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349, 368 (D. Mass. 2004); *In re Relafen Antitrust Litig.*, 2005 WL 418086, at *17, *21 (D. Mass. Feb. 22, 2005). Significantly, none of the *In re Relafen* opinions discusses whether state law *Walker Process* claims are preempted. In both *Intel Corp. v. Via Techs., Inc.*, 2001 WL 777085, at *6 (N.D. Cal. Mar. 20, 2001) and *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 540, 549 (D.N.J. 2000), district courts allowed state law claims to proceed where the only ground on which the parties moved to dismiss was that the state law claims were dependent on the survival of related federal antitrust claims, which were not dismissed. Similarly, in *FDI, Inc. v. W.R. Grace & Co., Inc.*, 1980 WL 1996, *3-4 (C.D. Cal. Sept. 29, 1980), the court refused to grant summary judgment on portions of plaintiff's federal *Walker Process* antitrust and related unfair competition claim based on the same allegations, although preemption is not discussed in the opinion. Thus, although indirect plaintiffs have cited several cases in which state law claims based at least in part on misconduct before the PTO have been permitted to proceed, they have at least to some extent involved non-PTO conduct. In any event, none of them is binding precedent, and none of them cites any reason why such claims are not preempted by federal patent law.

Argument, 2/28/2005. They cite *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 369-73 (S.D.N.Y. 2002), in support of the proposition that such Orange Book filings can be used as a basis for a state law action. The issue before the court in *Buspirone* was whether the Orange Book filings were protected activity under the *Noerr-Pennington* doctrine. *See Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965). The district court held that the filings were not protected under *Noerr-Pennington*, but did not say one way or the other whether Orange Book listings constitute marketplace activity subjecting patent holders to state law antitrust remedies where the underlying alleged bad-faith conduct occurred before the PTO.

Even were one to assume that the Orange Book filing of the '444 Patent would provide a basis for a state law claim, this would not advance plaintiffs' cause here. There was nothing in the act of listing the '444 Patent in the Orange Book that was itself improper, *cf. In re Buspirone*, 185 F. Supp. 2d at 369-73, and the filing, according to plaintiffs, was only improper because Bayer was using it to maintain an allegedly ill-gotten patent. But this claim in turn depends first on a showing that the '444 Patent was obtained by fraud on the PTO. Plaintiffs cannot by this collateral or backdoor method avoid preemption of their state law claim.[28]

---

28. ssuming that the mere listing in the Orange Book constituted marketplace misconduct, it is highly unlikely that

(Cont'd)

(Cont'd)

indirect plaintiffs would be able to establish a *Walker Process* claim. Initially, *Walker Process* fraud requires a showing that the omission or misrepresentation to the Patent Office was so material that the patent would not have issued but for the omission or misrepresentation (a level of materiality referred to as "but for" materiality); consequently, a patent must be invalid before it can be a candidate for *Walker Process* fraud. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1365 (Fed. Cir. 1998) ("Indeed, since the inventorship issue was not grounds of invalidity, it cannot satisfy the "but for" test of fraud."); *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1070 (Fed. Cir. 1998) ("Such a misrepresentation or omission must evidence a clear intent to deceive the examiner and thereby cause the PTO to grant an *invalid* patent.") (emphasis added). In contrast, because the patent litigation defense of inequitable conduct does not require so high a level of materiality, it is possible for a patent to be unenforceable for inequitable conduct, but still valid. *See, e.g., Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1237 (Fed. Cir. 2003) (citing *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1322 (Fed. Cir. 2000). Indirect plaintiffs' reliance on *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341 (Fed. Cir. 2004) for the proposition that the materiality requirement for a showing of *Walker Process* fraud is met by simply pointing to the PTO's issuance of a patent is a gross misreading of the law. First, *Unitherm* did not depart from the standard set forth in *Nobelpharma* for showing "but for" materiality, and concluded: "Had the PTO not relied on this fraud, the Examiner would have reached the same conclusion as did the district court and this court . . . that no *valid* patent could issue from [the] application." *Unitherm*, 375 F.3d at 1361 (emphasis added). Second, if plaintiffs' assertion were correct – that simple issuance of a patent is sufficient to prove "but for" materiality - then the standard for proving *Walker Process* fraud materiality would be lower than the showing required for inequitable conduct and would, in fact, be met in every

(Cont'd)

Appendix C

Even if plaintiffs had made a sufficient showing of marketplace misconduct by Bayer in enforcing its '444 Patent to create an issue of fact, there is a serious question whether indirect plaintiffs have standing to

---

(Cont'd)

case. Such a conclusion is directly contrary to the Federal Circuit's holding in *Nobelpharma* and is not supported by *Unitherm*.

Furthermore, indirect plaintiffs cite eight instances of improper conduct before the PTO. Some have already been rejected by Judge Brewster as failing to establish invalidity (*see Bayer AG v. Carlsbad Tech., Inc.*, No. 01-cv-0867-B, slip op. at 6-7 (S.D. Cal. June 7, 2002)), some by the PTO during reexamination (Bayer Pat. App. Ex. 9) and others have been conceded as not rising to the level of "but for" materiality. More importantly, indirect plaintiffs did not adduce evidence of "but for" materiality for seven of these instances. The only instance for which their expert opined "but for" materiality was a claim that Bayer's statements regarding the superiority of the "compounds of the invention" to the prior art was misleading, because Bayer withheld data showing that certain of the claimed compounds were not, in fact, superior to the prior art. Lawyer advocacy or puffery is not a basis for granting or denying a patent claim. Superiority is not the issue. What is required instead is a showing of novelty and non-obviousness for a patent to issue, 35 U.S.C. §§ 102, 103, and for that the patent examiner is presumed to have relied on data, not attorney advocacy. *Cf. CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) ("During prosecution, an applicant may submit objective factual evidence to the PTO in the form of patents, technical literature, and declarations. . . . The advantages advocacy in this case does not fit any of these categories and was unaccompanied by and not asserted to be supported by any factual evidence. Therefore, a reasonable examiner would not have found it important in deciding whether to allow the application.")

assert a *Walker Process* claim. In *Asahi Glass*, Judge Posner, in *dicta*, assumed that a *Walker Process* claim is only available to a patentee's competitors. *Asahi Glass*, 289 F. Supp. 2d at 995 ("The claim of fraud on the patent office fails for the reason just given: if patent 723 was obtained by fraud, it was a fraud aimed at competing manufacturers of drugs, not at the suppliers of those manufacturers, and so the fraud claim cannot be pressed as an antitrust claim."). This view was earlier expressed by Judge Markey, later of the Federal Circuit, sitting by designation in *Oetiker v. Jurid Werke GmbH*, 671 F.2d 596, 599 (D.C. Cir. 1982) ("The Supreme Court has established that one guilty of fraudulent procurement and attempted enforcement of the patent thus procured may be liable for treble damages to *competitors* under the anti trust laws.") (citing *Walker Process*, 382 U.S. 172) (emphasis added). *See also In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522, 529 (D.N.J. 2004) ("*Walker Process* and its progeny involve antitrust counterclaimants who were potential or actual competitors in patent infringement suits. In this case, Plaintiffs, as direct purchasers, neither produced mirtazapine nor would have done so; moreover, Plaintiffs were not party to the initial patent infringement suits. Plaintiffs may not now claim standing to bring a *Walker Process* claim by donning the cloak of a Clayton Act monopolization claim.").

Finally, Bayer moves for summary judgment that Bayer's suits against Barr and the subsequent '444 Patent challengers were not sham litigation as a matter of law. To prove sham litigation, a plaintiff must show

(1) "the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits," and (2) that the litigant's "subjective motivation" for bringing the action was a sham seeking to conceal a knowing attempt to interfere with a competitor. *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61, 113 S.Ct. 1920, 1928, 123 L.Ed.2d 611 (1993). Here, Bayer's success in its litigations against Schein, Mylan and Carlsbad forecloses any argument that its lawsuits were shams. *See id.*, 508 U.S. at 61 n.5, 113 S.Ct. 1928 n.5 ("A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham."). Indirect plaintiffs' argument that Bayer's successes in the post-Barr litigations are immaterial, since the '444 Patent had by then undergone reexamination, is unconvincing. As discussed *supra*, reexamination does not cure inequitable conduct, and the defense was available to all of the generic challengers. *Molins v. Textron*, 48 F.3d at 1182.

In any event, as Bayer's motion to dismiss Count V is granted on the preemption ground, it is not necessary to reach the question of whether indirect plaintiffs' state law *Walker Process*-type claims and sham litigation claim are barred by the statute of limitations.

Appendix C

Conclusion

Applying a rule of reason analysis, the first element antitrust plaintiffs must prove is that the challenged agreements had an actual adverse effect on competition in the relevant market. Here, plaintiffs have failed to demonstrate anti-competitive effects in the market for ciprofloxacin because, although the Agreements undoubtedly restrained competition, they did not do so beyond the scope of the claims of the '444 Patent. The '444 Patent allows a zone of exclusion within the bounds of its claims, and that zone is undiminished by any potential invalidity of the claims. This result is compelled by the presumption of validity Congress accorded patents and the destabilizing effect on patent law that a contrary decision would work. Any readjustment of the competing interests affected by exclusion payments is a matter better addressed by Congress than the courts.

For the foregoing reasons,

- Bayer's Motion for Partial Summary Judgment on Plaintiffs' Claims Under the Sherman Act and Corresponding State Law Claims is granted;

- Generic Defendants' Motion for Summary Judgment is granted;

- Direct Purchaser Plaintiffs' Motion for Partial Summary Judgment is denied;

- Bayer's Motion to Dismiss Count V of the Indirect Purchaser Complaint Based on Threshold Grounds is granted;

- Bayer's Motion for Partial Summary Judgment on Count V of the Indirect Purchaser Class Plaintiffs' Proposed Second Amended Consolidated Class Action Complaint is dismissed as moot;

- HMR and Rugby's motion for summary judgment is dismissed as moot;

- Direct plaintiffs' amended complaints are dismissed;

- Indirect plaintiffs' second amended consolidated class action complaint is dismissed;

- Plaintiffs' motions for class certifications are denied as moot.

The Clerk of the Court is directed to close this case.

Dated: Brooklyn, New York
March 31, 2005

SO ORDERED:

/s/
David G. Trager
United States District Judge

APPENDIX D — PERTINENT TEXT OF RELEVANT STATUTES

SHERMAN ANTITRUST ACT

Section 1: Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

15 U.S.C. § 1.

DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984 ("HATCH-WAXMAN ACT"), AS AMENDED

* * *

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

* * *

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

* * *

(B) Notice of opinion that patent is invalid or will not be infringed

(i) *Agreement to give notice.* An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) *Timing of notice.* An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) *Recipients of notice.* An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) *Contents of notice.* A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been

submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

* * *

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on-(aa) the date on which the court enters judgment reflecting the decision; or (bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or (bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271 (e)(4)(A) of Title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II). In such an

action, each of the parties shall reasonably cooperate in expediting the action.

(iv) *180-day exclusivity period*

(I) *Effectiveness of application.* Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) *Definitions.* In this paragraph:

(aa) *180-day exclusivity period.* The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) *First applicant.* As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) *Substantially complete application.* As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) *Tentative approval*

(AA) *In general*

The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) *Limitation*

A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(C) *Civil action to obtain patent certainty*

(i) *Declaratory judgment absent infringement action*

Appendix D

(I) *In general*

No action may be brought under section 2201 of Title 28, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) *Filing of civil action*

If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (1) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against

the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) *Offer of confidential access to application*

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other

terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) *Counterclaim to infringement action*

(I) *In general*

If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

Appendix D

(II) *No independent cause of action*

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) *No damages.* An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) *Forfeiture of 180-day exclusivity period*

(i) *Definition of forfeiture event.* In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) *Failure to market.* The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative

approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of *certiorari*) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.

(II) *Withdrawal of application.* The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) *Amendment of certification.* The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) *Failure to obtain tentative approval.* The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) *Agreement with another applicant, the listed drug application holder, or a patent owner.* The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of *certiorari*) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of Title 15, except that the term includes section 45 of Title 15 to the extent that that section applies to unfair methods of competition).

(VI) *Expiration of all patents.* All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) *Forfeiture.* The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) *Subsequent applicant.* If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in paragraph (2) (A) (vii) (IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall

be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The

approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than

bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

* * *

21 U.S.C. § 355(j).

(June 25, 1938, c. 675, § 505, 52 Stat. 1052; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; June 25, 1948, c. 646, § 32(b), 62 Stat. 991; May 24, 1949, c. 139, § 127, 63 Stat. 107; 1953 Reorg. Plan

No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; June 11, 1960, Pub. L. 86-507, § 1 (18),74 Stat. 201; Oct. 10, 1962, Pub. L. 87- 781, Title I, §§ 102(b) to (d), 103(a), (b), 104(a) to (d)(2), 76 Stat. 781-783, 784, 785; Aug. 16, 1972, Pub. L. 92-387, § 4(d), 86 Stat. 562; Sept. 24, 1984, Pub. L. 98-417, Title I, §§ 101, 102(a) to (b)(5), 103, 104, 98 Stat. 1585, 1592, 1593, 1597; May 13, 1992, Pub. L. 102-282, § 5, 106 Stat. 161; Aug. 13, 1993, Pub. L. 103-80, § 3(n), 107 Stat. 777; Nov. 21, 1997, Pub. L. 105-115, Title I, §§ 115(a), (b), 117, 119, 120, 124(a), 111 Stat. 2313, 2315, 2316, 2318, 2324; Nov. 29, 1999, Pub. L. 106-113, Div. B, § 1000(a)(9) [Title IV, § 4732(b)(11)], 113 Stat. 1536, 1501A-584; Jan. 4, 2002, Pub. L. 107-109, § 15(c)(1), 115 Stat. 1420; Dec. 3, 2003, Pub. L. 108-155, § 2(b)(1), 117 Stat. 1941; Dec. 8, 2003, Pub. L. 108-173, Title XI, §§ 1101 (a), (b), 1102(a), 1103(a), 117 Stat. 2448, 2452, 2457, 2460.)

MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003

SEC. 1112. NOTIFICATION OF AGREEMENTS.

(a) AGREEMENT WITH BRAND NAME DRUG COMPANY.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act and a brand name drug company that enter into an agreement described in

paragraph (2) shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of the generic drug that is the subject of the ANDA.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph between a generic drug applicant and a brand name drug company is an agreement regarding—

(A) the manufacture, marketing or sale of the brand name drug that is the listed drug in the ANDA involved;

(B) the manufacture, marketing, or sale of the generic drug for which the ANDA was submitted; or

(C) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to such ANDA or to any other ANDA based on the same brand name drug.

(b) AGREEMENT WITH ANOTHER GENERIC DRUG APPLICANT.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act with respect to a listed drug and another generic drug applicant that has submitted an ANDA containing such a certification for the same listed drug shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior

to the date of the first commercial marketing of either of the generic drugs for which such ANDAs were submitted.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph between two generic drug applicants is an agreement regarding the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to the ANDAs with which the agreement is concerned.

(c) FILING.—

(1) AGREEMENT.—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text of any such agreement, except that such parties are not required to file an agreement that solely concerns

(A) purchase orders for raw material supplies;

(B) equipment and facility contracts;

(C) employment or consulting contracts; or

(D) packaging and labeling contracts.

(2) OTHER AGREEMENTS.—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text

of any agreements between the parties that are not described in such subsections and are contingent upon, provide a contingent condition for, or are otherwise related to an agreement that is required in subsection (a) or (b) to be filed in accordance with this subsection.

(3) DESCRIPTION.—In the event that any agreement required in subsection (a) or (b) to be filed in accordance with this subsection has not been reduced to text, each of the parties involved shall file written descriptions of such agreement that are sufficient to disclose all the terms and conditions of the agreement.

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1101-1104, 1111-1118, 117 Stat. 2066, 2448-2464 (2003).

* * *

THE PATENT ACT

Sec. 282. Presumption of validity; defenses

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)

(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b) (1). The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:

(1) Noninfringement, absence of liability for infringement or unenforceability,

(2) Invalidity of the patent or any claim in suit on any ground specified in part II of this title as a condition for patentability,

(3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of sections 112 or 251 of this title,

(4) Any other fact or act made a defense by this title.

In actions involving the validity or infringement of a patent the party asserting invalidity or noninfringement shall give notice in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any publication to be relied upon as anticipation of the patent in suit or, except in actions in the United States Court of Federal Claims, as showing the state of the art, and the name and address of any

person who may be relied upon as the prior inventor or as having prior knowledge of or as having previously used or offered for sale the invention of the patent in suit. In the absence of such notice proof of the said matters may not be made at the trial except on such terms as the court requires. Invalidity of the extension of a patent term or any portion thereof under section 154(b) or 156 of this title because of the material failure--

(1) by the applicant for the extension, or

(2) by the Director,

to comply with the requirements of such section shall be a defense in any action involving the infringement of a patent during the period of the extension of its term and shall be pleaded. A due diligence determination under section 156(d) (2) is not subject to review in such an action.

35 U.S.C. § 282.

(July 19, 1952, ch. 950, 66 Stat. 812; Pub. L. 89-83, Sec. 10, July 24, 1965, 79 Stat. 261; Pub. L. 94-131, Sec. 10, Nov. 14, 1975, 89 Stat. 692; Pub. L. 97-164, title I, Sec. 161 (7), Apr. 2, 1982, 96 Stat. 49; Pub. L. 98-417, title II, Sec. 203, Sept. 24, 1984, 98 Stat. 1603; Pub. L. 102-572, title IX, Sec. 902(b) (1), Oct. 29, 1992, 106 Stat. 4516; Pub. L. 104-41, Sec. 2, Nov. 1, 1995, 109 Stat. 352; Pub. L. 106-113, div. B, Sec. 1000(a) (9) [title IV, Secs. 4402 (b) (1), 4732 (a) (10) (A)], Nov. 29, 1999, 113 Stat. 1536, 1501A-560, 1501A-582; Pub. L. 107-273, div. C, title III, Sec. 13206(b) (1) (B), (4), Nov. 2, 2002, 116 Stat. 1906.)

181

(9)

Supreme Court, U.S.
FILED
FEB 4 - 2011
OFFICE OF THE CLERK

No. 10-762

IN THE

Supreme Court of the United States

LOUISIANA WHOLESALE DRUG CO., INC., *ET AL.*,
Petitioners,

v.

BAYER AG, *ET AL.*,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF IN OPPOSITION OF RESPONDENTS BARR LABORATORIES, INC., HOECHST MARION ROUSSEL, INC., WATSON PHARMACEUTICALS, INC., and THE RUGBY GROUP, INC.

DAVID E. EVERSON
HEATHER S. WOODSON
VICTORIA L. SMITH
STINSON MORRISON HECKER LLP
1201 Walnut Street
Kansas City, MO 64106
(816) 842-8600

CHRISTOPHER LANDAU, P.C.
Counsel of Record
KAREN N. WALKER, P.C.
EDWIN JOHN U
GREGORY L. SKIDMORE
KIRKLAND & ELLIS LLP
655 Fifteenth St., N.W.
Washington, DC 20005
(202) 879-5000
clandau@kirkland.com

February 4, 2011

TABLE OF CONTENTS

Page

INTRODUCTION 1

COUNTERSTATEMENT OF THE CASE 2

A. Factual Background 2

B. Procedural History 4

REASONS FOR DENYING THE WRIT 7

I. The Decision Below Is Correct. 7

II. The Decision Below Does Not Conflict With Decisions Of Other Courts Of Appeals 11

A. The Sixth and D.C. Circuits 12

B. The Eleventh Circuit 14

III. The Decision Below Does Not Conflict With This Court's Decisions. 17

A. Patent cases 17

B. Antitrust cases 20

IV. The Decision Below Does Not Warrant This Court's Review In The Absence Of A Conflict. ... 21

CONCLUSION 23

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, respondents state as follows:

1. Respondent Barr Laboratories, Inc. was wholly owned by Barr Pharmaceuticals, Inc. In December 2008, Barr Pharmaceuticals, Inc. was merged into a wholly owned subsidiary of Teva Pharmaceuticals USA, Inc., which itself is an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., a publicly held company. After the merger, the surviving company changed its name to Barr Pharmaceuticals LLC. No publicly held company other than Teva Pharmaceutical Industries Ltd. directly or indirectly owns 10% or more of the stock of Barr Pharmaceuticals LLC.

2. Respondent Hoechst Marion Roussel, Inc. has been merged and its pertinent assets and liabilities now reside with sanofi-aventis U.S. LLC. Sanofi-aventis U.S. LLC is owned by Sanofi-Synthelabo Inc. and Aventis Pharmaceuticals Inc., which are not publicly held. No other publicly held corporation owns 10% or more of its stock. Sanofi-Synthelabo Inc. and Aventis Pharmaceuticals Inc. are ultimately owned by sanofi-aventis, which is publicly held.

3. Respondent Watson Pharmaceuticals, Inc. is a publicly held corporation. No publicly held corporation owns 10% or more of its stock.

4. Respondent The Rugby Group, Inc. is a subsidiary of respondent Watson Pharmaceuticals, Inc. No other publicly held corporation owns 10% or more of its stock.

TABLE OF AUTHORITIES

Page(s)

Cases

Andrx Pharms., Inc. v. Biovail Corp. Int'l,
256 F.3d 799 (D.C. Cir. 2001).....11

Andrx Pharms., Inc. v. Kroger Co.,
543 U.S. 939 (2004).....1, 13

Arkansas Carpenters Health & Welfare Fund v. Bayer AG,
129 S. Ct. 2828 (2009) 1, 6

Asahi Glass Co. v. Pentech Pharms., Inc.,
289 F. Supp. 2d 986 (N.D. Ill. 2003) 9, 10, 18

Bayer AG v. Carlsbad Tech., Inc.,
No. 01 CV0867-B
(S.D. Cal. June 7, 2002 & Aug. 7, 2002) 3, 11

Bayer AG v. Schein Pharms., Inc.,
301 F.3d 1306 (Fed. Cir. 2002).....3, 11

Cardinal Chem. Co. v. Morton Int'l Inc.,
508 U.S. 83 (1993) 19

Dawson Chem. Co. v. Rohm & Haas Co.,
448 U.S. 176 (1980).....7

E. Bement & Sons v. National Harrow Co.,
186 U.S. 70 (1902) 7

eBay Inc. v. MercExchange, L.L.C.,
547 U.S. 388 (2006),.....19

Edward Katzinger Co. v. Chicago Metallic Mfg. Co.,
329 U.S. 394 (1947).....19

FTC v. Schering-Plough Corp.,
548 U.S. 919 (2006).....1, 14

In re Cardizem CD Antitrust Litig.,
332 F.3d 896 (6th Cir. 2003) 1, 11, 12, 13

In re Ciprofloxacin Hydrochloride Antitrust Litig.,
544 F.3d 1323 (Fed. Cir. 2008)....1, 5, 6, 12, 14, 15, 16, 18

In re Schering-Plough Corp.,
F.T.C. Docket No. 9297,
2003 WL 22989651 (F.T.C. Dec. 8, 2003),
vacated, 402 F.3d 1056 (11th Cir. 2005).....14

In re Tamoxifen Citrate Antitrust Litig.,
466 F.3d 187 (2d Cir. 2006).1, 4, 5, 6, 7, 10, 12, 13, 15, 18

Joblove v. Barr Labs., Inc.,
551 U.S. 1144 (2007).....1, 5, 22

Lear, Inc. v. Adkins,
395 U.S. 653 (1969).....19

Mallinckrodt, Inc. v. Medipart, Inc.,
976 F.2d 700 (Fed. Cir. 1992).....8

MedImmune, Inc. v. Genentech, Inc.,
549 U.S. 118 (2007).....20

Precision Instrument Mfg. Co. v. Automobile Maint. Mach. Co.,
324 U.S. 806 (1945).....7

Schering-Plough Corp. v. FTC,
402 F.3d 1056 (11th Cir. 2005) ...1, 8, 9, 10, 14, 16, 17, 18

Simpson v. Union Oil Co.,
377 U.S. 13 (1964) 20

United States v. General Elec. Co.,
272 U.S. 476 (1926).....8, 21

United States v. Glaxo Group Ltd.,
410 U.S. 52 (1973) 11, 21

United States v. Singer Mfg. Co.,
374 U.S. 174 (1963).....8, 21

Valley Drug Co. v. Geneva Pharms., Inc.,
344 F.3d 1294 (11th Cir. 2003) .1, 9, 10, 11, 14, 15, 16, 17, 18

Valley Drug Co. v. Geneva Pharms., Inc.,
543 U.S. 939 (2004).....1

Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.,
382 U.S. 172 (1965).....21

Constitution, Statutes, and Rules

21 U.S.C. § 355 3

28 U.S.C. § 1295(a)(1) 5

28 U.S.C. § 1407 4

35 U.S.C. § 154(a)(1) 7

35 U.S.C. § 282 9

Medicare Prescription Drug Improvement and Modernization Act of 2003,
Pub. L. No. 108-173, 117 Stat. 2066 22

S. Ct. R. 10.....14

U.S. Const. Art. I § 8 cl. 8 7

Other Authorities

Br. for the U.S. as Amicus Curiae,
FTC v. Schering-Plough Corp.,
No. 05-273 (U.S. May 17, 2006),
2006 WL 1358441 .....13, 15

Br. for the U.S. as Amicus Curiae, *Andrx Pharms., Inc. v. Kroger Co.*, No. 03-779 (U.S. July 9, 2004), 2004 WL 1562075 13

Br. for the U.S. as Amicus Curiae, *Joblove v. Barr Labs., Inc.*, No. 06-830 (U.S. May 23, 2007), 2007 WL 1511527 ..... 13, 22

H.R. 1432, 110th Cong. (2007) 22

H.R. 1706, 111th Cong. (2009) 22

H.R. 3962, 111th Cong. (2009) 22

S. 27, 112th Cong. (2011) 22

S. 316, 110th Cong. (2007) 22

S. 3582, 109th Cong. (2005) 22

S. 3677 (amend.), 111th Cong. (2010) 22

S. 369, 111th Cong. (2009) 22

INTRODUCTION

This is at least the sixth petition to urge this Court to resolve an alleged conflict among the federal courts of appeals that does not exist. According to petitioners, "[t]he circuits are split three ways" on whether there can be an unlawful restraint of competition entirely within a patent's exclusionary zone. Pet. 13. That assertion is incorrect, which may explain why this Court has denied each of the previous petitions alleging this same conflict—including a petition arising out of the very same district court decision at issue here. *See Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, No. 08-1194, 129 S. Ct. 2828 (2009) (declining to review *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), which affirmed the district court decision at issue here); *Joblove v. Barr Labs., Inc.*, No. 06-830, 551 U.S. 1144 (2007) (declining to review *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006)); *FTC v. Schering-Plough Corp.*, No. 05-273, 548 U.S. 919 (2006) (declining to review *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005)); *Valley Drug Co. v. Geneva Pharms., Inc.*, No. 03-1175, 543 U.S. 939 (2004) (declining to review *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003)); *Andrx Pharms., Inc. v. Kroger Co.*, No. 03-779, 543 U.S. 939 (2004) (declining to review *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003)). This Court should follow the same path here. Nothing has changed since this Court denied the previous petitions, except that the Second Circuit has declined to disturb the very same district court decision at issue here and its own *Tamoxifen* decision, both of which this Court has previously declined to review.

The ruling below, moreover, is manifestly correct. The whole point of a patent is to encourage and reward invention by giving inventors a monopoly over their inventions for a limited time. The owner of a valid patent is thus *entitled* to restrain competition within the patent's scope, and does not violate the antitrust laws by doing so, at least where the patent litigation was not an objective sham and the patent was not procured by fraud. There is simply no basis for courts to impose antitrust liability by second-guessing the settlement of legitimate patent litigation. That straightforward point is the beginning and the end of the matter.

Petitioners' policy arguments about the supposed adverse effects of patent settlements are thus directed to the wrong forum. Those who wish to subject such settlements to antitrust scrutiny are free to ask Congress to craft such a regime. And in fact they *have* asked Congress to craft such a regime, but Congress has declined to do so. Regardless of whether patent settlements are "controversial" as policy matter, Pet. 2, they are not "controversial" as a legal matter, as evidenced by petitioners' inability to identify any conflict among the circuits on this score. Accordingly, as in the previous cases raising this precise issue, this Court should once again deny *certiorari*.

COUNTERSTATEMENT OF THE CASE

A. Factual Background

This case involves a challenge to a settlement of patent litigation. Respondents Bayer AG and Bayer Corp. owned and licensed the patent to the active ingredient in the prescription antibiotic ciprofloxacin hydrochloride, commonly known as Cipro. Pet. App.

13a, 36-37a, 39-40a. When respondent Barr Laboratories, a generic drug manufacturer, sought FDA approval to introduce a competing generic version of the drug pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355, Bayer brought a patent infringement action, Pet. App. 15-16a, 40-41a. Because the Cipro patent covered the drug's active ingredient, Barr did not deny that the proposed generic would infringe the patent, but instead challenged the patent's validity. Given that Barr did not contest infringement and had not yet made any infringing sales, Barr's challenge to the patent's validity was the central issue in the litigation. Thus, for all intents and purposes, Barr was the plaintiff and Bayer the defendant in the lawsuit. Barr and Bayer litigated these patent issues against each other for five years. Pet. App. 15-16a, 41a.

In 1997, on the eve of trial, the parties settled the case. Pet. App. 16-17a, 41-42a. As part of the settlement agreement, Barr and its litigation partners received both monetary consideration and a license to sell a competing ciprofloxacin product at least six months before the Cipro patent expired. Pet. App. 16-17a, 41-42a. Nothing in that agreement purported to preclude other parties from challenging the validity of the Cipro patent, and indeed several other generic drug manufacturers proceeded to do so—unsuccessfully. *See, e.g., Bayer AG v. Schein Pharms., Inc.*, 301 F.3d 1306, 1312-23 (Fed. Cir. 2002) (upholding validity of Bayer's Cipro patent); *see also Bayer AG v. Carlsbad Tech., Inc.*, No. 01 CV0867-B (S.D. Cal. June 7, 2002 & Aug. 7, 2002) (same); Pet. App. 43a. Bayer itself also sought re-examination of the Cipro patent by the U.S. Patent & Trademark Office (PTO), which reaffirmed its

validity. Pet. App. 42-43a. The Cipro patent expired in 2003. Pet. App. 13a & n.1, 42a.

B. Procedural History

Petitioners are direct purchasers of Cipro. Starting in 2000, both direct and indirect purchasers began filing lawsuits against respondents challenging the 1997 Cipro settlement agreement as unlawfully anticompetitive. Pursuant to 28 U.S.C. § 1407, the lawsuits were transferred to the U.S. District Court for the Eastern District of New York.

After extended discovery, the district court (Trager, J.) granted summary judgment in respondents' favor, holding that the Cipro settlement agreement was lawful because it did not "constrain[] competition beyond the scope of the patent claims." Pet. App. 91a. "Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." Pet. App. 79a. In analyzing a challenge to the settlement agreement, the district court emphasized, "it would be inappropriate to engage in an after-the-fact analysis of the patent's likely validity." Pet. App. 89-90a.

Petitioners appealed to the Second Circuit. While the appeal was pending, that court decided *Tamoxifen*, in which it endorsed the district court's analysis in this case. *See* 466 F.3d at 211-13. Writing for the court, Judge Sack (joined by Judge Raggi) explained that "[w]hatever damage is done to competition by settlement is done pursuant to the monopoly extended to the patent holder by patent

law unless the terms of the settlement enlarge the scope of that monopoly." *Id.* at 212-13. The court block-quoted the legal standard established by the district court in this case: "'Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.'" *Id.* at 213 (quoting Pet. App. 79a). Judge Pooler dissented, arguing that courts can and should engage in "a more searching inquiry" into patent settlements challenged under the antitrust laws. *Id.* at 228 (dissenting opinion). This Court declined to review *Tamoxifen*. *See Joblove*, 551 U.S. 1144 (2007).

The Second Circuit thereafter transferred to the Federal Circuit one of the appeals arising out of the district court's decision in this case. *See* Order (11/7/07). As the Second Circuit explained, that appeal (by the indirect-purchaser plaintiffs) included a claim arising under the patent laws, and therefore fell within the Federal Circuit's exclusive appellate jurisdiction. *See id.*; *see generally* 28 U.S.C. § 1295(a)(1).

The Federal Circuit decided the transferred indirect-purchaser case before the Second Circuit even heard oral argument in this direct-purchaser case. *See Ciprofloxacin*, 544 F.3d 1323. The Federal Circuit affirmed the grant of summary judgment in respondents' favor, and endorsed the Second Circuit's reasoning in *Tamoxifen*. In particular, the Federal Circuit held that "the essence of the inquiry is whether the [settlement] agreements restrict competition beyond the exclusionary zone of the

patent," and that "in the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment." *Id.* at 1336. Because the plaintiffs raised no genuine issue of material fact regarding any restraint on competition beyond the exclusionary zone of the Cipro patent, and failed to establish either fraud on the PTO or sham litigation, defendants were entitled to summary judgment. *See id.* at 1331-37. This Court declined to review that decision. *See Arkansas Carpenters*, 129 S. Ct. 2828 (2009).

In a *per curiam* opinion, a panel of the Second Circuit (which included Judge Pooler, the dissenter in *Tamoxifen*) also affirmed the district court's decision in this case under *Tamoxifen*. *See* Pet. App. 9-35a. Because petitioners "do not argue that the patent infringement lawsuit was a sham or that the Cipro patent was procured by fraud, ... the only reasonable basis for distinguishing *Tamoxifen* would be if [petitioners] demonstrated that the settlement agreement here, unlike in *Tamoxifen*, exceeded the scope of the Cipro patent." Pet. App. 26a. But petitioners "cannot establish this because a generic version of Cipro would necessarily infringe Bayer's patent," which covered the drug's active ingredient. *Id.* "Thus, Barr's agreement to refrain from manufacturing generic Cipro encompasses only conduct that would infringe Bayer's patent rights," *id.*, and petitioners' antitrust claims necessarily fail as a matter of law. Although the panel recognized that the result in this case was dictated by *Tamoxifen*, the panel "invite[d]" petitioners "to petition for rehearing in banc." Pet. App. 35a.

Not surprisingly, petitioners accepted that invitation. The Second Circuit, however, denied the petition for rehearing *en banc* over the lone dissent of Judge Pooler. *See* Pet. App. 1-8a.

REASONS FOR DENYING THE WRIT

I. The Decision Below Is Correct.

The U.S. Constitution expressly authorizes Congress "[t]o promote the Progress of Science and useful Arts" by granting inventors "the exclusive Right" to their inventions "for limited Times." U.S. Const. Art. I § 8 cl. 8. Congress has exercised that authority by enacting the federal patent laws, which expressly grant patent holders "the right to exclude others from making, using, offering for sale, or selling the invention" for a limited period of time. 35 U.S.C. § 154(a)(1). "[T]he essence of a patent grant," as this Court has explained, "is the right to exclude others from profiting by the patented invention." *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980); *see also Precision Instrument Mfg. Co. v. Automobile Maint. Mach. Co.*, 324 U.S. 806, 816 (1945) ("[A] patent is an exception to the general rule against monopolies and to the right to access to a free and open market."); *E. Bement & Sons v. National Harrow Co.*, 186 U.S. 70, 91 (1902) ("The very object of [the patent] laws is monopoly.").

Because a patent confers the right to restrain competition within its exclusionary zone, by definition there can be no unlawful restraint of competition within that zone. "It is only when [a patent holder] steps *out* of the scope of his patent rights ... that he comes within the operation of the Anti-Trust Act." *United States v. General Elec. Co.*, 272 U.S. 476, 485 (1926) (emphasis added); *see also*

Schering-Plough, 402 F.3d at 1067 ("A patent holder does not incur antitrust liability when it chooses to exclude others from producing its patented work."); *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992) ("Should the restriction [on competition] be found to be reasonably within the patent grant, *i.e.*, that it relates to subject matter within the scope of the patent claims, that ends the [antitrust] inquiry."); *cf. United States v. Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963) ("[A] valid patent ... does not give the patentee any exemption from the provisions of the Sherman Act *beyond* the limits of the patent monopoly.") (emphasis added).

These points, as the Second Circuit recognized, dispose of this case. Petitioners "cannot establish" that the settlement agreement at issue here exceeded the scope of the Cipro patent "because a generic version of Cipro would necessarily infringe" the patent, which covered the active ciprofloxacin compound itself. Pet. App. 26a; *see also id.* ("Barr's agreement to refrain from manufacturing generic Cipro encompasses *only* conduct that would infringe Bayer's patent rights.") (emphasis added). Nor do petitioners contend that "the patent infringement lawsuit was a sham or that the Cipro patent was procured by fraud." *Id.* Accordingly, petitioners' challenge to the Cipro settlement agreement is necessarily a challenge to the monopoly granted by the Cipro patent, and fails as a matter of law.

Petitioners insist, however, that the Cipro settlement agreement violated the antitrust laws because the Cipro patent *might have been* invalid. *See* Pet. 2, 14-15, 22-23, 25-26. According to petitioners, the statutory presumption of patent

validity, *see* 35 U.S.C. § 282, is rebutted by a settlement agreement that includes a payment by the patent holder to the party challenging the patent's validity. *See* Pet. 4-5; *see also id.* at 23 ("[T]he fact that the brand made an exclusion payment is, at a minimum, sufficient evidence to satisfy the antitrust plaintiff's initial burden under the rule of reason."). A patent holder, petitioners assert, "would not have made the payment" if the patent were valid. Pet. 5.

That assertion is baseless. There are many reasons why parties settle litigation even if they believe they should and will prevail. For one thing, parties cannot know in advance if they will prevail; given the inherent uncertainty of litigation, "[n]o one can be *certain* that he will prevail in a patent suit." *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003) (Posner, J., by designation) (emphasis in original). Indeed, "[d]ue to the 'asymmetrics of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.'" *Schering-Plough*, 402 F.3d at 1075 (quoting *Valley Drug*, 344 F.3d at 1310). Petitioners' contrary approach essentially asks this Court to adopt a presumption of patent *invalidity* unknown, and contrary, to the law. Thus, whether the terms of a patent settlement agreement include a license, a payment, or both, such an agreement cannot subject the settling parties to treble-damages antitrust liability where (as here) the settlement does not exceed the scope of the patent, the patent litigation was not an objective sham, and the patent was not procured by fraud.

Prohibiting a lawsuit over patent validity—in contrast to any other type of lawsuit—from being settled for monetary consideration would discourage not only patent settlements but also challenges to patent validity. "A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive." *Asahi Glass*, 289 F. Supp. 2d at 994; *see also Tamoxifen*, 466 F.3d at 203 ("Rules severely restricting patent settlements might also be contrary to the goals of the patent laws because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents and might delay innovation.") (citing *Valley Drug*, 344 F.3d at 1308); *Schering-Plough*, 402 F.3d at 1075 ("[T]he caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer's ability to research, develop, and market the patented product or allegedly infringing product.").

Petitioners complain, however, that this regime allows patent holders to "muzzle" any challenge to the validity of their patents, *see* Pet. 26 (internal quotation omitted), and "buy a shield from judicial examination of the legitimacy of their patents," *id.* at 30. Again, petitioners are incorrect. The settlement of patent litigation resolves claims between the settling parties, but does not preclude *other* parties from challenging the patent's validity. Indeed, this case underscores the point: after the patent settlement at issue here, the patent's validity was challenged by other generic drugmakers—*unsuccessfully*. *See, e.g., Schein Pharms.*, 301 F.3d

at 1312-23; *Carlsbad Tech.*, No. 01 CV0867-B (S.D. Cal. June 7, 2002 & Aug. 7, 2002). Petitioners argue that a patent settlement "delays" any such additional challenges, Pet. 26, but such challenges can be brought at any time. Indeed, the Second Circuit rejected as "unpersuasive" petitioners' argument that the settlement agreement at issue here "caused other generic manufacturers to delay subsequent challenges." Pet. 27a. Moreover, under certain circumstances, the Government may even sue to cancel or annul a patent. *See, e.g.*, *United States v. Glaxo Group Ltd.*, 410 U.S. 52, 57-59 (1973). Petitioners' fundamental premise that a patent settlement allows a patent holder to "forgo judicial testing of the patent's validity," Pet. 2, is simply untrue.

II. The Decision Below Does Not Conflict With Decisions Of Other Courts Of Appeals.

Petitioners argue that this Court "should grant review because the circuit courts are divided over the standard for evaluating whether exclusion payments are anticompetitive." Pet. 13 (capitalization modified). In particular, petitioners allege that "[t]he circuits are split three ways" on this issue, *id.*, with (1) the Sixth and D.C. Circuits applying a "patent strength" standard, *id.* at 14-18 (citing *Cardizem*, 332 F.3d 896, and *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001)), (2) the Eleventh Circuit applying a "patent relitigation" approach, *see id.* at 18-20 (citing *Valley Drug*, 344 F.3d 1294), and (3) the Second and Federal Circuits applying the presumption of patent validity to settlement agreements within the scope of a patent, unless the patent was obtained by fraud or

the patent claim was a sham, *see id.* at 20-23 (citing, in addition to the decision below, *Tamoxifen*, 466 F.3d 187, and *Ciprofloxacin*, 544 F.3d 1323).

According to petitioners, the decision below "cannot be squared with those of other circuits." Pet. 2. Petitioners are wrong, and the "clear and wide" circuit conflict they allege, *id.* at 23, is illusory.

A. The Sixth and D.C. Circuits

Petitioners first assert that the decision below conflicts with *Cardizem*, in which the Sixth Circuit upheld a grant of partial summary judgment to plaintiffs challenging a patent settlement agreement. *See* Pet. 15-16. That assertion is incorrect; indeed, the Second Circuit in *Tamoxifen*, the Federal Circuit in *Ciprofloxacin*, and the district court in this case expressly negated any such conflict.

The settlement agreement at issue in *Cardizem* went *beyond* the scope of the patent monopoly; it "included not only a substantial reverse payment but also an agreement that the generic manufacturer would not market *non*-infringing products." *Tamoxifen*, 466 F.3d at 213-14 (emphasis added). It was thus "unlike the agreement" at issue in *Tamoxifen* (and here) which "did *not* extend the patent monopoly by restraining the introduction or marketing of unrelated or non-infringing products." *Id.* at 213 (emphasis added; citing *Cardizem*, 332 F.3d at 902, 908 & n.13); *see also* Pet. App. 59a ("The agreement at issue in [*Cardizem*] ... contained provisions that clearly exceeded any competitive restrictions accruing to the defendants under patent law."); *Ciprofloxacin*, 544 F.3d at 1335 (explaining that *Cardizem* is "distinguishable from this case" because the settlement agreement at issue there

"clearly had anticompetitive effects *outside* the exclusion zone of the patent") (emphasis added). Indeed, the United States has made this point repeatedly in recommending against review of the very circuit conflict alleged here. *See* Br. for the U.S. as Amicus Curiae, *Joblove v. Barr Labs., Inc.*, No. 06-830 (U.S. May 23, 2007), 2007 WL 1511527, at 16 n.7 ("*Cardizem* involved payments to exclude competition in drugs that did *not* fall within the scope of the allegedly infringed patent, and thus it is uncertain whether the per se rule employed by the Sixth Circuit extends beyond the unique circumstances of that case.") (emphasis in original); Br. for the U.S. as Amicus Curiae, *FTC v. Schering-Plough Corp.*, No. 05-273 (U.S. May 17, 2006), 2006 WL 1358441, at 16-17 (same); *see also id.* at 19 ("[T]he Second Circuit's decision [in *Tamoxifen*] did not involve drugs outside the patent claim and it thus does not create any split with the Sixth Circuit's *Cardizem* decision."); Br. for the U.S. as Amicus Curiae, *Andrx Pharms., Inc. v. Kroger Co.*, No. 03-779 (U.S. July 9, 2004), 2004 WL 1562075, at 11-15 (same).

Petitioners' argument that the decision below conflicts with the D.C. Circuit's decision in *Andrx* fails for the same reason. That case, as petitioners concede, involved "the same agreement that was at issue in *Cardizem*." Pet. 16. Because that agreement restrained competition *beyond* a patent's scope, it is readily distinguishable from the settlement agreement at issue here. *See Tamoxifen*,

466 F.3d at 213-14; *Ciprofloxacin*, 544 F.3d at 1335; Pet. App. 59-60a.[1]

B. The Eleventh Circuit

Petitioners next assert that the decision below conflicts with *Valley Drug*, in which the Eleventh Circuit reversed a grant of partial summary judgment to plaintiffs challenging a patent settlement agreement. *See* Pet. 18-20. Again, that assertion is incorrect.

Valley Drug, like the decision below, held that a settlement agreement resolving a challenge to patent validity does not violate the antitrust laws to the extent such an agreement does not exceed the patent's scope, at least insofar as the underlying patent litigation was not a sham and the patent was not procured by fraud. *See* 344 F.3d at 1308-10 & nn.21, 22. The Eleventh Circuit thus reversed a grant of partial summary judgment in the plaintiffs'

---

[1] Curiously, petitioners also argue that this Court should grant review on the ground that the decision below conflicts with an administrative decision by the Federal Trade Commission. *See* Pet. 17-18 (citing *In re Schering-Plough Corp.*, F.T.C. Docket No. 9297, 2003 WL 22989651 (F.T.C. Dec. 8, 2003), *vacated*, 402 F.3d 1056 (11th Cir. 2005)). That argument is, to put it mildly, a stretch. This Court has never identified an asserted conflict between an administrative enforcement agency and a court as a basis for review. *See* S. Ct. R. 10. That is not surprising, because administrative enforcement decisions are subject to judicial review in their own right. Indeed, the administrative decision on which petitioners rely was not only challenged but also *vacated* by the Eleventh Circuit on precisely the ground at issue here. *See Schering-Plough*, 402 F.3d at 1075-76. The FTC unsuccessfully sought this Court's review of the Eleventh Circuit's decision. *See* 548 U.S. 919 (2006).

favor, and remanded for the district court to determine whether the challenged agreements "have effects *beyond* the exclusionary effect of [the disputed] patent," in which case they "may then be subject to traditional antitrust analysis to assess their probable anticompetitive effects." *Id.* at 1312 (emphasis added); *see also id.* ("We recognize the patent exception to antitrust liability, but also recognize that the exception is limited by the terms of the patent and the statutory rights granted the patentee.").

That approach is entirely consistent with the approach followed by the Second and Federal Circuits, and indeed both of those courts (as well as the district court in this case) followed the Eleventh Circuit's approach. *See Ciprofloxacin*, 544 F.3d at 1335-37; *Tamoxifen*, 466 F.3d at 212-13; Pet. App. 24a, 54-58a. Again, the United States made this point in recommending against review of the very circuit conflict alleged here. *See* Br. for the U.S. as Amicus Curiae, *FTC v. Schering-Plough Corp.*, No. 05-273 (U.S. May 17, 2006), 2006 WL 1358441, at 19 ("Far from expressing any disagreement with the Eleventh Circuit's decision below, ... the Second Circuit explicitly approved of the Eleventh Circuit's focus on whether 'the exclusionary effects of the agreement exceed the scope of the patent's protection.'") (quoting *Tamoxifen*, 466 F.3d at 212).

Petitioners caricature *Valley Drug* as holding that "the lawfulness of an exclusion payment is determined by relitigating the patent issues as part of the antitrust case." Pet. 5; *see also id.* at 18 (asserting that the Eleventh Circuit requires courts to "engag[e] in an *ex-post* judicial determination of

the patent issues as part of the antitrust case"). The Eleventh Circuit held nothing of the sort, except insofar as it recognized—as have the Second and Federal Circuits—that a patent's scope is relevant to the antitrust analysis because a patent holder does not unlawfully restrain competition when acting within that scope. *See Valley Drug*, 344 F.3d at 1307-08; *see also Schering-Plough*, 402 F.3d at 1076 ("What we must focus on is the extent to which the exclusionary effects of the [settlement] agreement fall within the scope of the patent's protection.").

Contrary to petitioners' suggestion, *see* Pet. 18, the Eleventh Circuit did *not* hold that it is necessary or appropriate for courts to assess a patent's validity in resolving an antitrust challenge to a settlement agreement. Not surprisingly, petitioners cite nothing in *Valley Drug* so holding, and other courts have recognized that the Eleventh Circuit has *rejected* that approach. *See Ciprofloxacin*, 544 F.3d at 1336 ("[W]e agree with the Second and Eleventh Circuits and with the district court that, in the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment."); *id.* at 1336 n.12 ("[T]he Eleventh Circuit did *not* consider or rely on evidence of patent invalidity in ... *Valley Drug*.") (emphasis added); Pet. App. 54a ("The Eleventh Circuit in *Valley Drug* ... held that to the extent the effects of the subject settlement agreements are within the scope of the exclusionary potential of the patent, such effects are not subject to ... antitrust condemnation, *even where the patent is later held invalid*.") (emphasis added); *id.* at 56a ("[*Valley Drug*] reserved any *post hoc* validity analysis for

those cases in which the patent was procured by fraud or known by the patentee to be invalid.").

And even assuming that *Valley Drug* left any ambiguity on this score, the Eleventh Circuit dispelled any such ambiguity in *Schering-Plough*. As the Eleventh Circuit explained in that case, a patent's "validity" *vel non* has no bearing in the antitrust inquiry, as long as the agreement does not exceed the patent's scope. 402 F.3d at 1075.

III. The Decision Below Does Not Conflict With This Court's Decisions.

Petitioners further contend that "this Court should grant review because the Second Circuit's standard conflicts with this Court's precedents." Pet. 23 (capitalization modified). That is so, they assert, because "[t]he Second Circuit has elevated the rebuttable presumption of validity into an *ironclad right* of patentees to exclude competition." *Id.* (emphasis added). That assertion is manifestly incorrect, and the alleged conflict with this Court's patent and antitrust cases is fanciful.

A. Patent cases

Petitioners first argue that the decision below conflicts with a line of this Court's cases "emphasiz[ing] that judicial testing of patent validity is essential precisely because the issuance of a patent by the PTO was not intended to have—and does not have—the *conclusive significance* accorded by the Second Circuit." Pet. 25 (emphasis added)

The premise of that argument is incorrect: the Second Circuit never suggested that the statutory presumption of validity was "conclusive." *Id.* Rather, the Second Circuit recognized only that a

patent settlement, regardless of its terms, does not create a presumption of invalidity. *See Tamoxifen*, 466 F.3d at 203-04, 210; *see also Ciprofloxacin*, 544 F.3d at 1337; *Schering-Plough*, 402 F.3d at 1066-68; *Valley Drug*, 344 F.3d at 1306-08; Pet. App. 69-93a. Indeed, the Second Circuit has emphasized that the statutory presumption of patent validity is *not* the cornerstone of the analysis, and that "irrespective of whether there was a presumption," a patent holder is "entitled to protect its ... patent monopoly through settlement." *Tamoxifen*, 466 F.3d at 209 n.22.

Contrary to petitioners' assertion, there is no federal "policy in favor of judicial examination of patent validity," Pet. 30, that precludes parties from settling a challenge to patent validity. The federal patent laws neither compel anyone to challenge a patent's validity in the first place nor prohibit anyone from settling such a challenge on whatever terms the parties see fit, as long as such a settlement does not exceed the patent's scope. Contrary to petitioners' suggestion, *see* Pet. 9-10; *id.* at 25 n.9, there is no basis in law or logic for distinguishing between settlements that give a patent challenger a license and settlements that give a patent challenger a payment—*all* settlements involve consideration, and the form of that consideration has no bearing on the lawfulness of the settlement. *See, e.g.*, *Asahi Glass*, 289 F. Supp. 2d at 994 ("*[A]ny* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement.") (emphasis in original).

The cases on which petitioners rely are wholly inapposite. The issue in both *Edward Katzinger Co.*

v. Chicago Metallic Mfg. Co., 329 U.S. 394 (1947), and *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), was whether a patent licensee was estopped from challenging the patent's validity. This Court held in both cases that the federal patent laws did not create any such estoppel, *see* 329 U.S. at 399-401, 395 U.S. at 669-70, but did not remotely suggest that a licensee (or anyone else) is either compelled to launch such a challenge or precluded from settling it on terms the parties see fit.

The issue in *Cardinal Chem. Co. v. Morton Int'l Inc.*, 508 U.S. 83 (1993) was whether a determination of patent non-infringement precluded a court from reaching the issue of patent validity. In holding that courts were entitled to reach the validity issue, this Court noted that the enforcement of invalid patents is undesirable, *see id.* at 101-02 & n.24, but did not suggest that this unremarkable point either compels anyone to challenge patent validity or precludes anyone from settling such a challenge on terms the parties see fit.

The issue in *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006), was whether a patent holder is automatically entitled to enjoin an infringer, or must satisfy the traditional standard for obtaining such equitable relief. By holding that the patent laws do not obviate the need to meet the traditional standard, *see id.* at 391-92, this Court did not call into question the statutory presumption of patent validity, or suggest that anyone is either compelled to challenge patent validity or precluded from settling such a challenge on terms the parties see fit.

And the issue in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), was whether a licensee had

standing to challenge a patent's validity without terminating or breaching the license agreement. In holding that a licensee did have such standing, *see id.* at 130-36, the Court again did not suggest that anyone is compelled to challenge patent validity or precluded from settling such a challenge on terms the parties see fit.

It is thus not true that the decision below "conflicts with this Court's patent cases." Pet. 24. Petitioners simply wrench snippets of language out of context and describe those cases at a level of generality that has no bearing on the issue presented here.

B. Antitrust cases

Petitioners next argue that the decision below "violates this Court's fundamental antitrust principles," insofar as "this Court has held that it is anticompetitive for a firm to pay a competitor to exit or stay out of the market." Pet. 30.

But the cases on which petitioners rely in support of that argument are inapposite, because they do not involve competition within the scope of a patent. As noted above, this Court has long recognized that the patent laws "are in pari materia with the antitrust laws and modify them pro tanto." *Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964). Antitrust cases outside the patent context thus shed no light on the issue presented here, and certainly do not give rise to the "conflict" alleged by petitioners.

Not surprisingly, therefore, petitioners beat a hasty retreat from that alleged "conflict" to the more modest assertion that "this Court has never afforded patentees antitrust immunity for paying competitors

not to try to overcome them." Pet. 31. But that assertion proves nothing, as it is equally true that this Court has never held that a settlement agreement renders a patent presumptively invalid. Leaving patent holders subject to antitrust liability even for a settlement that does not exceed the patent's scope, does not involve sham litigation, or does not involve a patent procured by fraud would upset the balance between the patent and antitrust laws that has always been the polestar of this Court's jurisprudence in this area. *See, e.g.*, *Glaxo*, 410 U.S. at 58; *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 179-80 (1965) (Harlan, J., concurring); *Singer*, 374 U.S. at 189, 196-97; *General Electric*, 272 U.S. at 485.

IV. The Decision Below Does Not Warrant This Court's Review In The Absence Of A Conflict.

Because the decision below does not conflict with any decision of another court of appeals or this Court, petitioners are ultimately left with nothing more than an argument that patent settlements of the type at issue here represent bad public policy. In essence, petitioners contend that the public policy favoring competition (which underlies the antitrust laws) should trump the public policy favoring innovation (which underlies the patent laws) so as to allow antitrust claims within the scope of a patent. In our democratic system, however, such far-reaching policy arguments must be directed to Congress, not the courts.

And such policy arguments *have* been directed to Congress—repeatedly. Numerous bills have been introduced in recent years that would have altered

the law governing patent settlements. *See, e.g.*, S. 27, 112th Cong. (2011); S. 3677 (amend.), 111th Cong. (2010); S. 369, 111th Cong. (2009); H.R. 3962, 111th Cong. (2009); H.R. 1706, 111th Cong. (2009); S. 316, 110th Cong. (2007); H.R. 1432, 110th Cong. (2007); S. 3582, 109th Cong. (2005). None of these bills, however, has passed. Needless to say, in the absence of a conflict, there is no basis for the judicial branch to take up policy arguments on which the political branches are fully engaged.

Indeed, legislative action taken during the pendency of this case makes this a poor vehicle to address petitioners' arguments. Congress amended the Hatch-Waxman Act in 2003 in ways that addressed some of petitioners' theories of competitive harm. *See* Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. As the United States noted in recommending against *certiorari* in *Tamoxifen* (another case governed by the pre-2003 regime), the 2003 amendments "altered the regulatory dynamic" in relevant ways, and thereby make it "preferable" to address the question presented in *Tamoxifen* (and here), if at all, "in a case that arises under the current regulatory regime." Br. for the U.S. as Amicus Curiae, *Joblove v. Barr Labs., Inc.*, No. 06-830 (U.S. May 23, 2007), 2007 WL 1511527, at 19-20.

And petitioners' insistence that patent settlements of the type at issue here are "routine[]" and "not abating," Pet. 2, 35, only underscores that it would be imprudent for this Court to grant review at this juncture. If indeed patent settlement agreements are as "controversial" as petitioners suggest, Pet. 2, then a conflict can be expected to

develop as the issue percolates among the lower courts. It is neither necessary nor appropriate for this Court now to jump into the fray.

CONCLUSION

For the foregoing reasons, this Court should deny the petition for writ of certiorari.

Respectfully submitted,

DAVID E. EVERSON
HEATHER S. WOODSON
VICTORIA L. SMITH
STINSON MORRISON
HECKER LLP
1201 Walnut Street
Kansas City, MO 64106
(816) 842-8600

Counsel for Respondents Hoechst Marion Roussel, Inc., Watson Pharmaceuticals, Inc., and The Rugby Group, Inc.

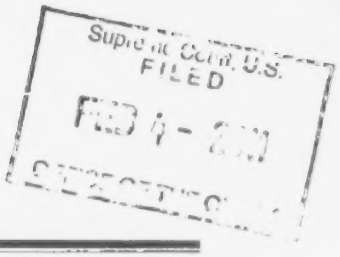
CHRISTOPHER LANDAU, P.C.
Counsel of Record
KAREN N. WALKER, P.C.
EDWIN JOHN U
GREGORY L. SKIDMORE
KIRKLAND & ELLIS LLP
655 Fifteenth St., N.W.
Washington, DC 20005
(202) 879-5000

Counsel for Respondent Barr Laboratories, Inc.

February 4, 2011

181

(10)



No. 10–762

IN THE

Supreme Court of the United States

LOUISIANA WHOLESALE DRUG CO., INC., CVS PHARMACY, INC., RITE AID CORPORATION, ARTHUR'S DRUG STORE, INC.,

Petitioners,

v.

BAYER AG, BAYER CORP., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., WATSON PHARMACEUTICALS, INC., BARR LABORATORIES, INC.,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit

RESPONDENTS BAYER AG & BAYER CORP.'S BRIEF IN OPPOSITION

PHILLIP A. PROGER
KEVIN D. MCDONALD
LAWRENCE D. ROSENBERG
CHRISTOPHER S. PERRY
MARK R. LENTZ
JONES DAY
51 Louisiana Ave , N.W.
Washington, D.C. 20001
(202) 879-3939

FRED H. BARTLIT, JR.
Counsel of Record
PETER B. BENSINGER, JR.
MICHAEL J. VALAIK
PAUL J. SKIERMONT
BARTLIT BECK HERMAN PALENCHAR & SCOTT LLP
54 West Hubbard St.
Chicago, IL 60654
(312) 494-4400
fred.bartlit@bartlit-beck.com

February 4, 2011

COUNSEL FOR RESPONDENTS BAYER AG & BAYER CORP.

QUESTION PRESENTED

Whether settlement of patent litigation that excludes no more competition than the exclusionary scope of the patent gives rise to antitrust liability where (1) patent infringement was conceded, and (2) the antitrust plaintiff does not allege that the patent was invalid, unenforceable, procured by fraud, or asserted in sham litigation.

CORPORATE DISCLOSURE STATEMENT

Bayer Corporation is a wholly-owned subsidiary of Bayer AG. There is no publicly-held company that owns more than 10% of Bayer AG.

TABLE OF CONTENTS

Page

QUESTION PRESENTED i

CORPORATE DISCLOSURE STATEMENT ii

TABLE OF AUTHORITIES v

INTRODUCTION 1

COUNTERSTATEMENT OF THE CASE 2

REASONS FOR DENYING THE PETITION 10

I. THERE IS NO CONFLICT OF AUTHORITY 10

A. The Second Circuit Ruling Does Not Conflict With Any Appellate Decision 11

B. Petitioners' Circuit Split Argument Ignores The Language Of The Cases 13

II. FUNDAMENTAL ANTITRUST PRINCIPLES SUPPORT THE RULE ADOPTED BELOW 21

A. The "Scope of The Patent" Rule Is Correct 21

B. The Ruling Below Does Not Conflict With This Court's Precedents 24

C. Petitioners' And Amici's "Policy" Arguments Are Unsupported and Unpersuasive 27

III. THIS CASE IS A POOR VEHICLE TO RESOLVE THE QUESTION PRESENTED 31

CONCLUSION 36

APPENDIX A: Affidavit of Raymond Rasimas (May 26, 2004) 1a

APPENDIX B: Plaintiffs' Memorandum Of Law In Opposition To All Defendants' Motions To Dismiss The Indirect Purchaser Class Plaintiffs Complaints (May 22, 2002) 3a

APPENDIX C: Memorandum Of Direct Purchaser Plaintiffs In Opposition To Defendants' Motions For Summary Judgment (July 9, 2004)..... 7a

TABLE OF AUTHORITIES

Page(s)

CASES

Access Telecom, Inc. v. MCI Telecommc'ns Corp.,
197 F.3d 694 (5th Cir. 1999) 22

Andrx Pharmaceuticals, Inc. v. Biovail, Corp.,
256 F.3d 799 (D.C. Cir. 2001) 14, 15

Andrx Pharms., Inc. v. Kroger Co.,
543 U.S 939 (2004) 16, 21

Arkansas Carpenters Health & Welfare Fund v. Bayer AG,
604 F.3d 98 (2d Cir. 2010) ..... *passim*

Asahi Glass Co. v. *Pentech Pharms., Inc.*,
289 F. Supp. 2d 986 (N.D. Ill. 2003) 13, 22

Bayer AG v. Schein Pharm., Inc.,
129 F. Supp. 2d 705 (D.N.J. 2001), *aff'd*
301 F.3d 1306 (Fed. Cir. 2002) 6, 35

Bement v. Nat'l Harrow Co.,
186 U.S. 70 (1902) 21

Dawson Chem. Co. v. Rohm & Haas Co.,
448 U.S. 176 (1980) 21

eBay Inc. v. MercExchange, L.L.C.,
547 U.S. 388 (2006) 26

Eli Lilly & Co. v. Medtronic, Inc.,
496 U.S. 661 (1990) 3

FTC v. Schering-Plough Corp.,
548 U.S. 919 (2006) 16, 18, 20, 21

In re Androgel Antitrust Litig.,
687 F. Supp. 2d 1371 (N.D. Ga. 2010)..... 13, 20

In re Canadian Import Antitrust Litig.,
470 F.3d 785 (8th Cir. 2006)..... 22

In re Cardizem CD Antitrust Litig.,
332 F.3d 896 (6th Cir. 2003), *cert. denied*,
543 U.S. 939 (2004)..... *passim*

In re Ciprofloxacin Hydrochloride Antitrust Litig.,
166 F. Supp. 2d 740 (E.D.N.Y. 2001) 6-7

In re Ciprofloxacin Hydrochloride Antitrust Litig.,
261 F. Supp. 2d 188 (E.D.N.Y. 2003) 4, 7, 17, 23

In re Ciprofloxacin Hydrochloride Antitrust Litig.,
363 F. Supp. 2d 514 (E.D.N.Y. 2005) ..... *passim*

In re Ciprofloxacin Hydrochloride Antitrust Litig.,
544 F.3d 1323 (Fed. Cir. 2008), *cert. denied*,
129 S. Ct. 2828 (2009)..... *passim*

In re K-Dur Antitrust Litig.,
No. 01-1652, 2010 WL 1172995 (D.N.J. Mar. 25, 2010)..... 13

Joblove v. Barr Labs., Inc. (In re Tamoxifen Citrate Antitrust Litig.),
466 F.3d 187 (2d Cir. 2006), *cert. denied*,
551 U.S. 1144 (2007)..... *passim*

King Drug Co. v. Cephalon, Inc.,
702 F. Supp. 2d 514 (E.D. Pa. 2010) 13

Lear, Inc. v. Adkins,
395 U.S. 653 (1969)..... 26

Leegin Creative Leather Prods., Inc. v. PSKS, Inc.,
551 U.S. 877 (2007) 2

Mallinckrodt, Inc. v. Medipart, Inc.,
976 F.2d 700 (Fed. Cir. 1992) 22

Medimmune, Inc. v. Genentech, Inc.,
549 U.S. 118 (2007) 26

Miroyan v. United States,
439 U.S. 1338 (1978) 21

The Monrosa v. Carbon Black Export, Inc.,
359 U.S. 180 (1959) 34

Preiser v. Newkirk,
422 U.S. 395 (1975) 34

Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co.,
154 F. 358 (7th Cir. 1907) 21

Schering-Plough Corp. v. FTC,
402 F.3d 1056 (11th Cir. 2005) ..... *passim*

SCM Corp. v. Xerox Corp.,
645 F.2d 1195 (2d Cir. 1981) 22-23

Standard Oil Co. v. United States,
283 U.S. 163 (1931) 2, 26

United States v. Studiengesellschaft Kohle, m.b.H.,
670 F.2d 1122 (D.C. Cir. 1981) 21, 22

USM Corp. v. SPS Techs., Inc.,
694 F.2d 505 (7th Cir. 1982) 22

Valley Drug Co. v. Geneva Pharms., Inc.,
344 F.3d 1294 (11th Cir. 2003), *cert. denied*,
543 U.S. 939 (2004) ..... *passim*

Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.,
382 U.S. 172 (1965) ..... *passim*

CONSTITUTIONAL AUTHORITIES AND STATUTES

21 U.S.C. § 355(j)(2) 3

21 U.S.C. § 355(j)(5) 3, 4, 33

35 U.S.C. § 154 ..... 2, 21

35 U.S.C. § 271(e) 3, 23

Drug Price Competition and Patent Term Restoration Act,
Pub. L. No. 98-417, 98 Stat. 1585 (1984) 2-3

Medicare Prescription Drug, Improvement, and Modernization Act of 2003,
Pub. L. No. 108-173, 117 Stat. 2066 ..... 4, 31

Preserve Access to Affordable Generics Act,
S. 27, 112th Cong. (2011) 4, 34

Preserve Access to Affordable Generics Act,
S. 369, 111th Cong. (2009) 4, 34

Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009) 4, 34

Supplemental Appropriations Act of 2010,
H.R. 4899, 111th Cong. (2010) 34

U.S. Const., art. I, § 8, cl. 8 2

OTHER AUTHORITIES

149 Cong. Rec. 31200 (2003) 33

149 Cong. Rec. 31783 (2003) 33

David Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*,
55 FOOD & DRUG L.J. 321 (2000) 32

Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 Fed. Cir. B.J. 617 (2006) 27

Anjan Chatterji & Xiang Yu, *Impact of Reverse Exclusionary Settlements on Consumer Welfare: A Law and Economic Analysis*, 23 Antitrust Health Care Chronicle, July 2010 29

Bret Dickey et al., *A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on 'Reverse Payment' Settlements* (2010), *available at* http://newsroom.law360.com/articlefiles/186893-Analysis.pdf 29

Natalie M. Derzko, *The Impact Of Recent Reforms Of The Hatch-Waxman Scheme On Orange Book Strategic Behavior And Pharmaceutical Innovation*, 45 IDEA 165 (2005) 33

FDA, Drugs: First-Time Generics – June 2004, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/UCM063712.htm 5

Federal Trade Commission, Agreements Filed With FTC Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2006, *available at* http://www.ftc.gov/reports/mmact/MMArepoM2006pt.pdf 28-29

Federal Trade Commission, Agreements Filed With FTC Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2007, *available at* http://www.ftc.gov/os/2008/05/mmact/MMArMMAre2006.pdf 28

Federal Trade Commission, Agreements Filed With FTC Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2008, *available at* http://www.ftc.gov/os/2010/01/100113-mpdim2003rpt.pdf 28

Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study (2002) *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf 30

Federal Trade Commission, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions: An FTC Staff Study (2010) *available at* www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf 29

Gregory Glass, *Why Settle?*, UPDATE, Sept.-Oct. 2005 30

Adam Greene & D. Dewey Steadman, *Pharmaceuticals, Analyzing Litigation Success Rates*, RBC CAptial Markets (2010) *available at* http://amlawdaily.typepad.com/pharmareport.pdf 30

Eugene Gressman et al., Supreme Court Practice (9th ed. 2007) 31

Herbert Hovenkamp et al., IP and Antitrust § 7.4 (2004) 32

H.R. Rep. No. 98-857, pt. 1 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647 4

INTRODUCTION

The law is that a patent owner can exclude infringing competition within the patent's exclusionary effect. Here, Bayer settled patent litigation in which infringement was conceded and the settlement excluded only competition within the patent's exclusionary effect.

The Second Circuit held below that Bayer had no antitrust liability because the settlement was within the scope of the patent and the Petitioners did not contend that Bayer procured its patent by fraud or asserted it in sham litigation. Nor could they. After the settlement, the validity of Bayer's patent was upheld by the Patent Office on reexamination, in three district court challenges, and on appeals to the Federal Circuit.

The ruling below does not conflict with the decisions of any other court of appeals. As the Solicitor General has advised the Court several times, there is no circuit split on the question presented, and cases like this one that arose under the prior regulatory regime that Congress amended in 2003 do not present good vehicles for review. This Court denied certiorari in all of those cases, and nothing has occurred to alter the analysis. On the contrary, the Federal Circuit has since affirmed the same order of the same district court on an appeal by a different group of plaintiffs, and this Court again denied certiorari, without seeking the views of the United States. Making no new arguments, the present Petition misreads the same caselaw and misstates the same facts. The Court should deny certiorari, just as it did before.

COUNTERSTATEMENT OF THE CASE

Statutory And Regulatory Background

1. The Sherman Act and the Patent Act each promote competition, but through different means. The Sherman Act protects competition, not competitors, by prohibiting monopolization and unreasonable restraints on trade. *See Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 906 (2007). The Patent Act promotes competition by rewarding the innovation that leads to new and better products. It does so through the patent's grant of "the right to exclude others." U.S. Const., art. I, § 8, cl. 8; 35 U.S.C. § 154. When patentees pursue that right through litigation, this Court has long embraced the policy favoring settlement of patent suits. *E.g., Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931).

In *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), the Court sought to achieve "a suitable accommodation ... between the differing policies of the patent and antitrust laws" when the patentee's conduct is within the scope of the subject patent. *Id.* at 179 (Harlan, J., concurring). *Walker Process* held that proof of fraud in securing a patent "would be sufficient to strip [the patentee] of its exemption from the antitrust laws." *Id.* at 177. Beyond such intentional misconduct, however, the patentee's "good faith would furnish *a complete defense*" to antitrust claims. *Id.* (emphasis added).

2. a. The Drug Price Competition and Patent Term Restoration Act, or the "Hatch-Waxman Act," addresses the interaction between patent protection

and generic drugs. Pub. L. No. 98-417, 98 Stat. 1585 (1984). Under Hatch-Waxman, a prospective generic drug manufacturer filing an Abbreviated New Drug Application ("ANDA") must demonstrate that the "active ingredient of the new drug is the same as that of the listed [or innovator's] drug." 21 U.S.C. § 355(j)(2)(A)(ii)(I). This enables the generic to avoid the time and expense of conducting its own clinical trials. The statute also gave the first generic ANDA filer 180 days of market exclusivity before another generic could enter the market. *Id.* § 355(j)(5)(B)(iv).

To protect the rights of patentees, the statute requires an ANDA filer seeking FDA approval before expiration of any patent claiming the listed drug to certify that the patent "is invalid or ... will not be infringed." 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification"). The ANDA filer must then notify the patent holder of its Paragraph IV Certification. *Id.* § 355(j)(5)(B)(iii).

Under Hatch-Waxman, the ANDA filing is an "artificial" act of patent infringement even though the filer has made no infringing sales. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990); 35 U.S.C. § 271(e)(2)(A). If the innovator drug manufacturer sues for infringement within 45 days of receipt of notice of the ANDA filing, then the FDA is stayed for 30 months from approving the ANDA. *Id.*

Hatch-Waxman thereby changed the risks of ordinary patent litigation. In traditional litigation, the accused infringer risks paying damages for its infringing sales. In ANDA litigation, however, the generic challenger has no risk of paying damages, as it can challenge the patent without entering the market. Thus, its exposure is limited to litigation

costs. Yet, the innovator can have billions at risk. As a result, settlements with the innovator paying the generic challenger — so-called "reverse payment" settlements — are "a natural by-product of the Hatch-Waxman process." *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003) ("*Cipro II*").

Although Hatch-Waxman changed the risk allocation, it did not otherwise alter patent litigation. Nothing in Hatch-Waxman was "intended to modify existing patent law with respect to the burden of proof and the nature of the proof to be considered by the courts in determining whether a patent is valid or infringed." H.R. Rep. No. 98-857, pt. 1, at 28 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2661.

b. Congress amended Hatch-Waxman in 2003. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. Congress changed the provisions governing the first-filer's 180-day exclusivity period (21 U.S.C. § 355(j)(5)(B)(iv)(I)) and required that parties settling ANDA litigation submit their settlement agreements to the FTC (*id.* § 355(j)(5)(D)(i)(V)).

Since 2003, legislation has been introduced to change the antitrust framework applicable to reverse-payment settlements. *See, e.g.*, S. 27, 112th Cong. (2011); S. 369, 111th Cong. (2009); H.R. 1706, 111th Cong. (2009). In the last Congress, the House passed such bills twice, as did two Senate Committees, but none was finally enacted.

Background Of The Case

1. Bayer owns U.S. Patent No. 4,670,444 ("'444" or the "Cipro Patent"). Pet. App. 13a. Claim 12 of the Cipro Patent covers the ciprofloxacin molecule, which is the drug's active ingredient. Because a generic drug must have the same active ingredient as the innovator, all formulations of generic Cipro would infringe Bayer's patent. *See id.* at 39a-40a.

The Cipro Patent expired on December 9, 2003. *Id.* at 13a. The FDA granted Bayer an additional six months of "pediatric exclusivity." *Id.* n.1. After Bayer's patent and pediatric exclusivity ended on June 9, 2004, generic Cipro became widely available. *See* FDA, Drugs: First-Time Generics – June 2004, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/UCM063712.htm (last visited Feb. 3, 2011).

2. In 1991, Barr Laboratories, Inc. ("Barr") notified Bayer that it had filed an ANDA seeking to market generic Cipro before '444's expiration. Pet. App. 13a. There was "no dispute that Barr's product would have infringed Bayer's [compound] patent," so Barr alleged that '444 was invalid and unenforceable. *Id.* 40a.

Bayer sued Barr for patent infringement in the Southern District of New York. *Id.* at 15a-16a. Thereafter, The Rugby Group, Inc. ("Rugby"), a subsidiary of Hoechst Marion Roussel, Inc. ("HMR"), entered into a "Litigation Funding Agreement" with Barr. *Id.* at 41a. (HMR later sold Rugby to Respondent Watson Pharmaceuticals, Inc.)

Shortly before trial, Bayer and Barr settled. *Id.* at 16a-17a. Barr agreed to a Consent Judgment affirming '444's validity and to amend its ANDA such that it could market generic Cipro only after '444 expired. In exchange, Bayer agreed to license a competing ciprofloxacin product at least six months before Bayer's patent expired. Bayer also had the option to grant a longer license or to make settlement payments over a six-year period. Bayer chose to make payments, which ultimately totaled $398.1 million, or 6.5% of Bayer's U.S. gross sales of oral Cipro tablets for the payment period. Supp. App. 2a.

After settling, Bayer submitted '444 to the U.S. Patent and Trademark Office ("PTO") for reexamination. *See* Pet. App. 42a-43a. The PTO confirmed the validity of claim 12 covering the ciprofloxacin molecule. *Id.*

Also after the settlement, four generic drug manufacturers filed ANDAs seeking to market generic Cipro (Ranbaxy, Mylan, Schein, and Carlsbad). *Id.* at 17a n.9. Bayer sued each for infringement. The Ranbaxy challenge was dismissed as moot after Ranbaxy withdrew its ANDA. Bayer defeated Schein and Mylan on summary judgment, and the Federal Circuit affirmed. *Bayer AG v. Schein Pharm., Inc.*, 129 F. Supp. 2d 705 (D.N.J. 2001), *aff'd*, 301 F.3d 1306 (Fed. Cir. 2002). Bayer won a bench trial against Carlsbad, which did not appeal.

3. a. Starting in 2000, direct and indirect purchasers of Cipro filed antitrust challenges to the settlement. Pet. App. 17a. The MDL Panel consolidated those cases before the late Judge David Trager in the Eastern District of New York. *See In re*

Ciprofloxacin Hydrochloride Antitrust Litig., 166 F. Supp. 2d 740, 745 (E.D.N.Y. 2001) ("*Cipro I*").

In 2003, Judge Trager denied all Plaintiffs' motions for partial summary judgment, rejecting their argument that the settlement was per se unlawful. *Cipro II*, 261 F. Supp. 2d 188. The Indirect Purchaser Plaintiffs later amended their complaint to add a state-law *Walker Process* claim based on fraud before the PTO. Pet. App. 37a. The Direct Purchaser Plaintiffs — Petitioners here — did not amend their complaints.

In 2005, Judge Trager granted judgment for Defendants on all claims. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005) ("*Cipro III*"), Pet. App. 36a. He held, "[u]nless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." Pet. App. 79a (citations omitted). Because "plaintiffs ha[d] not shown that the [Settlement] Agreements had anti-competitive effects beyond the scope of the '444 Patent," their claims failed. *Id.* at 92a-93a. Judge Trager also dismissed the state-law *Walker Process* claim as preempted by federal patent law and noted that no fraud on the PTO had occurred. *Id.* at 104a n.28, 108a.

All Plaintiffs appealed to the Second Circuit. The Second Circuit transferred the Indirect Purchasers' appeal to the Federal Circuit due to their *Walker Process* claim (*see id.* at 20a n.10), but retained the Direct Purchasers' appeals.

b. Shortly after Plaintiffs appealed, the Second Circuit decided a different Hatch-Waxman case, in which it adopted Judge Trager's legal analysis and cited his *Cipro* opinions seventeen times. *Joblove v. Barr Labs., Inc. (In re Tamoxifen Citrate Antitrust Litig.)*, 466 F.3d 187 (2d Cir. 2006). *Tamoxifen* found that the alleged "reverse payment" was not suspect, but rather consistent with "the patent holder's incentive to settle the lawsuit ... even when it is relatively confident of the validity of its patent." *Id.* at 210. *Tamoxifen* then adopted its governing rule directly from Judge Trager: "Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." *Id.* at 213 (quoting *Cipro III*, 363 F. Supp. 2d at 535, Pet. App. 79a).

The Second Circuit denied rehearing en banc, and this Court denied certiorari. 551 U.S. 1144 (2007).

c. In 2008, a unanimous Federal Circuit panel affirmed Judge Trager's ruling in the appeal transferred from the Second Circuit. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) ("*Cipro IV*"). The Court reaffirmed the rule that Judge Trager and other circuits applied:

> [I]n cases such as this, wherein all anticompetitive effects of the settlement agreement are within the exclusionary power of the patent, the outcome is the same whether the court begins its analysis under antitrust law by applying a rule of

> reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent. The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent. This analysis has been adopted by the Second and the Eleventh Circuits and by the district court below and we find it to be completely consistent with Supreme Court precedent."

Id. at 1336 (citing *Walker Process*, 382 U.S. at 175-77).

The Federal Circuit found that Judge Trager's approach was consistent with other circuits' precedents and that, absent fraud or sham litigation, "the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment." *Id.* at 1334-36. The Court also found that the settlement did not create a "bottleneck" delaying other generics or precluding their market entry. *Id.* at 1338.

The Federal Circuit also agreed with Judge Trager that federal law preempted the state-law *Walker Process* claim. In so holding, the Court found that Bayer had not committed fraud on the PTO: "[T]he district court determined, *and we agree*, that no fraud occurred." *Id.* at 1341 (emphasis added).

The Federal Circuit denied rehearing en banc, and this Court denied certiorari. 129 S. Ct. 2828 (2009).

d. On April 29, 2010, in this appeal, the Second Circuit likewise affirmed Judge Trager's ruling. *See*

Pet. App. 24a-25a. Under *Tamoxifen*, there could be no "injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." *Id.* at 25a.

Nonetheless, the panel "invite[d] plaintiffs-appellants to petition for in banc rehearing." *Id.* at 35a. This invitation was based in part on a mistaken reading of *Tamoxifen* and the pre-amendment, 2003 version of the Hatch-Waxman Act, which governs this case. Bayer moved to correct the opinion.

The panel granted Bayer's motion in part and corrected its opinion on June 17, 2010. *See Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010), Pet. App. 9a. Afterward, the full Second Circuit denied the petition for rehearing en banc without calling for a response from Respondents. Pet. App. 2a. The panel's presiding judge, Rosemary Pooler, filed a lone dissent from denial of rehearing en banc. *Id.* at 3a. This Petition followed.

REASONS FOR DENYING THE PETITION

Nothing has changed to merit review since this Court denied certiorari to review the Federal Circuit's affirmance of the same district court ruling at issue. There is no split in the circuits, the rule applied below flows directly from this Court's precedents, and this case presents a poor vehicle for resolving the question presented.

I. THERE IS NO CONFLICT OF AUTHORITY

The Second, Eleventh, and Federal Circuits all agree that, absent fraud on the PTO or sham litigation, patent settlements within the exclusionary scope of the patent are lawful.

Petitioners conjure a supposed "three way" circuit split by invoking the same cases that the Indirect Purchasers advanced when this Court declined to review the Federal Circuit's decision in this case. In fact, every case that Petitioners claim is in conflict with the ruling below issued before the Solicitor General last advised the Court that no conflict exists.

A. The Second Circuit Ruling Does Not Conflict With Any Appellate Decision

The circuits consistently have applied the "scope of the patent" rule to Hatch-Waxman settlements. Indeed, all of the circuits to have addressed reverse payment settlements — even the Sixth Circuit, on which Petitioners principally rely — have cited with approval Judge Trager's reasoning in this case. *See Tamoxifen*, 466 F.3d at 213; *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1068 (11th Cir. 2005); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1306 (11th Cir. 2003); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 n.13 (6th Cir. 2003).

Here, the Second Circuit applied the controlling rule that there could be no "injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." Pet. App. 25a (quoting *Tamoxifen*, 466 F.3d at 213) (further citation omitted). The settlement could not have "exceeded the scope of the Cipro patent," since "a generic version of Cipro would necessarily infringe Bayer's patent." *Id.* at 26a. Here, moreover, "Plaintiffs do not argue that the patent infringement lawsuit was a sham or that the Cipro patent was procured by fraud." Pet. App. 26a.

The Second Circuit's rulings in this case and in *Tamoxifen* are wholly consistent with the Federal Circuit's *Cipro* decision as well. The Federal Circuit held that "[t]he essence of the [antitrust] inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent." *Cipro IV*, 544 F.3d at 1336. Where the settlement is within the patent's scope, and there is no "evidence of fraud on the PTO or sham litigation," there is no antitrust violation. *Id.* at 1335. As the court explained, "[t]his analysis has been adopted by the Second and Eleventh Circuits and by the district court below and we find it to be completely consistent with Supreme Court precedent." *Id.* at 1336 (citing *Walker Process*, 382 U.S. at 175-77).

In reaching their decisions, the Second and Federal Circuits also relied upon the Eleventh Circuit's decisions in *Schering-Plough* and *Valley Drug*. *See* Pet. App. 24a (citing *Schering-Plough*, 402 F.3d at 1076); *Cipro IV*, 544 F.3d at 1333-37. In those decisions, the Eleventh Circuit held that the "exclusionary effect of the patent" is the starting point for the antitrust analysis. *Valley Drug*, 344 F.3d at 1306 (internal quotation marks omitted); *Schering-Plough*, 402 F.3d at 1068. Applying that standard, the Eleventh Circuit held in *Schering-Plough* that, because there was no allegation of sham litigation or fraud on the PTO, "the proper analysis now turns to whether ... the challenged agreements restrict competition beyond the exclusionary effects of the ... patent." 402 F.3d at 1068. [1]

---

[1] The Eleventh Circuit in *Schering-Plough*, like the Second Circuit in *Tamoxifen* and the Federal Circuit in *Cipro IV*, cited

Since this Court denied certiorari in *Cipro IV*, three more district courts have acknowledged the consensus among the circuits and adopted the scope of the patent rule. *See In re K-Dur Antitrust Litig.*, No. 01-1652, 2010 WL 1172995 (D.N.J. Mar. 25, 2010) (Order adopting Special Master's Amended Report and Recommendations, *available at* 2009 WL 508869, at *27 (D.N.J. Feb. 6, 2009)) (Third Circuit Judge Greenaway, sitting by designation); *In re Androgel Antitrust Litig.*, 687 F. Supp. 2d 1371, 1379 (N.D. Ga. 2010); *King Drug Co. v. Cephalon, Inc.*, 702 F. Supp. 2d 514 (E.D. Pa. 2010) (applying rule of *Tamoxifen* and *Cipro IV*, but denying a motion to dismiss because complaints alleged that the settlements exceeded the patent's scope).

B. Petitioners' Circuit Split Argument Ignores The Language Of The Cases

1. *The Sixth and D.C. Circuits.* Contrary to Petitioners' assertion, neither the Sixth Circuit nor the District of Columbia Circuit "have adopted the 'patent strength' standard," which supposedly bases liability "on the patent litigants' own view of the likely outcome of the [patent] litigation" being settled. *See* Pet. 14-18. Ignoring the analysis of these cases, Petitioners staple together partial quotations, none of which articulates Petitioners' purported standard, nor uses the term "patent strength" to describe it.

---

with approval Judge Posner's analysis in *Asahi Glass Co. v. Pentech Pharmaceuticals, Inc.*, 289 F. Supp. 2d 986 (N.D. Ill. 2003), which also applied the "objectively baseless" test. *Schering-Plough*, 402 F.3d at 1074-75; *Tamoxifen*, 466 F.3d at 208-10; *Cipro IV*, 544 F.3d at 1337.

The Sixth Circuit's decision in *Cardizem* and the D.C. Circuit's decision in *Andrx Pharmaceuticals, Inc. v. Biovail, Corp.*, 256 F.3d 799 (D.C. Cir. 2001), analyzed the same settlement arising from litigation about the drug Cardizem. Every court to discuss the facts has observed that the settlement at issue imposed restraints *beyond* the exclusionary scope of the patent.

In the Cardizem settlement, the generic manufacturer agreed not to market even "non-infringing formulations" and to block other generic entrants through manipulating the 180-day exclusivity period. *See Cardizem*, 332 F.3d at 902; *Andrx*, 256 F.3d at 804. In contrast, the Cipro Patent covers all formulations of generic Cipro and Barr agreed to amend its ANDA, removing any obstacle to other generics. Thus, the Sixth and D.C. Circuit decisions are fully consistent with the decision below and other circuit decisions. *See, e.g.*, *Tamoxifen*, 466 F.3d at 214; *Valley-Drug*, 344 F.3d at 1311 n.26.

Andrx, moreover, is entirely inapposite. The D.C. Circuit did not even address the legality of reverse payments, much less hold them to be per se illegal. Rather, the court considered whether a dismissal for lack of antitrust injury was appropriate. The court found that it was, but should not have been with prejudice. *Andrx*, 256 F.3d at 801. The passage Petitioners quote (Pet. 17) was in the section of the *Andrx* opinion discussing "Antitrust Injury" (256 F.3d at 812) and the court was accepting for purposes of that discussion the "alleg[ation] that Andrx entered into an anticompetitive *agreement* with HMRI in order to exclude others." *Id.* at 813. In addressing "but for" injury, the court simply rejected defendants'

argument that Andrx would not have actually entered the market, even though it planned to do so.[2]

Unlike the D.C. Circuit in *Andrx*, the Sixth Circuit in *Cardizem* did rule on the legality of the patent settlement before it, but not using the analytical framework Petitioners urge. Thus, when Petitioners quote the sentence in *Cardizem* stating that a patentee may not "bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market" (Pet. 16), they exclude a key footnote in that very sentence citing Judge Trager's analysis in *Cipro* with approval. *Cardizem*, 332 F.3d at 908 n.13. In the footnote Petitioners omit, the Sixth Circuit adopted Judge Trager's analysis of why *Cardizem* was distinguishable from *Cipro* — because the Cardizem settlement covered non-infringing products, and thus exceeded the scope of the patent:

> As the court in *In re Ciprofloxacin* observed, ["][w]hen the Cardizem [district] court condemned the HMR/Andrx Agreement, it emphasized that the agreement [there] restrained

---

[2] No court has read *Andrx* as containing a holding concerning the legality of reverse payments. The Cipro Indirect Purchasers who sought certiorari from the Federal Circuit did not cite or discuss *Andrx* in the section of their Petition arguing that there is a circuit split. Petition for Certiorari at 19-24, *Cipro IV*, 129 S. Ct. 2828 (2009) (No. 08-1194), 2009 WL 797579. Nor did Judge Pooler cite *Andrx* in dissenting from the denial of en banc review below and asserting that there was a "conflict among the Courts of Appeals." Pet. App. 8a. Not even the Sixth Circuit in *Cardizem* — decided a full two years after *Andrx* — so much as mentioned it. *See Cardizem*, 332 F.3d at 899-915.

> Andrx from marketing other bioequivalent or generic versions of Cardizem that were not at issue in the pending litigation[.] Thus, the court found that the agreement's restrictions extended to noninfringing and/or potentially noninfringing versions of generic Cardizem.["]

332 F.3d at 908 n.13 (first, fifth, and sixth alterations added).

When this Court sought the views of the Solicitor General regarding certiorari in *Cardizem*, he explained that the Sixth Circuit did not adopt a per se rule against payments. Rather, the agreement there prohibited the "marketing not only of allegedly infringing products but also of non-infringing or potentially non-infringing products that were not at issue in the patent litigation." Brief for United States as Amicus Curiae at 7, 13-15, *Andrx Pharms., Inc. v. Kroger Co.*, 543 U.S 939 (2004) (No. 03-779), 2004 WL 1562075 ("Cardizem Br."). As support, the Solicitor General relied expressly on the *Cardizem* footnote citing Judge Trager's opinion. *Id.* at 14-15.

Since then, the Court has twice more sought the Solicitor General's views, and twice more been told that *Cardizem* presents no conflict. Brief for United States as Amicus Curiae at 16 n.7, *Joblove v. Barr Labs., Inc.*, 551 U.S. 1144 (2007) (No. 06-830), 2007 WL 1511527 ("Tamoxifen Br.") (distinguishing *Cardizem* and citing Cardizem Br. at 16-17); Brief for the United States as Amicus Curiae at 16-17, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273), 2006 WL 1358441 ("Schering-Plough Br.").

Every circuit that has discussed the Cardizem settlement has recognized that it went beyond the exclusionary effect of the patent. The Federal Circuit noted that "the [Cardizem] agreement provided that the generic manufacturer would not market non-infringing versions of the generic drug," and thus, "clearly had anticompetitive effects outside the exclusion zone of the patent." *Cipro IV*, 544 F.3d at 1335. The Second Circuit also distinguished *Cardizem*, emphasizing that under the Cardizem agreement, "the generic manufacturer would not market non-infringing products." *Tamoxifen*, 466 F.3d at 214. The Eleventh Circuit agreed that certain provisions of the Cardizem agreements "seem to exceed the potential exclusionary power of the patent." *Valley Drug*, 344 F.3d at 1311 n.26.

2. *The Eleventh Circuit.* Petitioners contend that the Eleventh Circuit has adopted a different standard calling for "an ex-post judicial determination of the patent issues" (Pet. 18), in which the merits of the patent claim would "be relitigated as part of the antitrust case" (*id.* at 13). The cases are to the contrary.

In *Valley Drug*, the Eleventh Circuit faulted the district court for "fail[ing] to consider the exclusionary power of Abbott's patent in its antitrust analysis." 344 F.3d at 1306. Quoting *Cipro II* with approval, *Valley Drug* asserted that "the exclusionary effect of the patent must be considered *before* making any determination as to whether the alleged restraint is *per se* illegal." *Id.* (quoting *Cipro II*, 261 F. Supp. 2d at 249) (emphasis added).

With respect to settlements within the patent's exclusionary effect, the Eleventh Circuit expressly

rejected the argument that the merits of the patent claim should be "relitigated": "[E]xposing settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid would undermine the patent incentives." 344 F.3d at 1308. The court noted the potential for a "sham" exception (*id.* at 1308-09 & n.21), but found that it would not apply because "appellees have demonstrated nothing more than subsequent invalidity." *Id.* at 1309.

Valley Drug involved an "interim settlement" that did not resolve the ongoing patent case, which continued and later found the patent invalid. 344 F.3d at 1300-01. Thus, when *Valley Drug* issued, there was nothing to "relitigate." The patent had been held invalid, and the patent owner was estopped from contesting invalidity. This is why the FTC subsequently told this Court that any "suggestion that a post hoc inquiry into the patent merits would satisfy the [Eleventh Circuit] is *disingenuous* because *Valley Drug* squarely precludes a conclusion of liability on that basis." Reply Br. for Petitioner at 2, *Schering-Plough*, 548 U.S. 919 (No. 05-273), 2005 WL 2652617 (citation omitted and emphasis added).

Petitioners' argument here is based exclusively on statements made in Section "D" of the *Valley Drug* opinion, where the court considered the allegation that the settlement agreement went *beyond* the scope of the patent. 344 F.3d at 1311. In doing so, the court emphasized that "[t]o the extent these or other effects of the Agreements are *within* the scope of the exclusionary potential of the patent, such effects are *not* subject to *per se* antitrust condemnation." *Id.* at

1311 (emphases added). The court added that "[a]pplication of rule of reason analysis is similarly inappropriate, as the anticompetitive effects of exclusion cannot be seriously debated." *Id.* n.27.

But the rule of reason analysis *could* apply to settlement provisions that went beyond the scope of the patent. It was in that respect only that *Valley Drug* suggested that the district court consider "the likelihood of [the innovator's] obtaining" similar protections via "the preliminary injunction and stay mechanisms." *Id.* at 1312. That dicta cannot change the court's express holding with respect to conduct within the patent's scope.

Nor did *Schering-Plough* change the law of the Eleventh Circuit. 402 F.3d at 1065 ("We are bound by our decision in *Valley Drug*"). After noting that there were no allegations of invalidity or sham litigation, *Schering-Plough* stated that "the proper analysis now turns to whether ... the challenged agreements restrict competition beyond the exclusionary effects of the '743 patent." *Id.* at 1068 (citing *Valley Drug*, 344 F.3d at 1306).

Petitioner's argument with respect to *Schering-Plough* is based on a single phrase in the opinion's conclusion, stating that a legal ban on settlement payments would ignore "the need to evaluate the strength of the patent." 402 F.3d at 1076. If taken as an endorsement of "relitigating" the patent merits in an antitrust case, the statement would conflict not only with *Valley Drug*, but with the analysis of *Schering-Plough* itself.

Earlier in *Schering-Plough*, the Eleventh Circuit expressly equated the patent's exclusionary effect

with the scope of the patent claims. *Id.* at 1073 ("The '743 patent claims a 'controlled release microencapsulated potassium chloride tablet.' The language in the Schering-Upsher agreement covers the identical reach of the '743 patent."). The Court also stated on the same page as the "strength" reference that "the agreements fell well within the protections of the '743 patent, and were therefore not illegal." *Id.* at 1076. Judge Trager properly rejected Petitioners' misreading of those words, concluding that "this admonition [in *Schering-Plough*] is more fairly read as requiring an evaluation of the scope of the patent's claims, and not a *post hoc* analysis of the patent's validity." *Cipro III*, 363 F. Supp. 2d at 539, Pet. App. 89a.

When this Court sought the views of the United States regarding certiorari in *Schering-Plough*, the Solicitor General considered the decisions in the Sixth and Eleventh Circuits, as well as the Second Circuit's intervening decision in *Tamoxifen*. Schering-Plough Br. at 16-20. The United States concluded that "there is no circuit split justifying this Court's review." *Id.* at 16.[3]

In sum, the circuit cases are in harmony, uniformly citing Judge Trager's *Cipro* analysis with approval. Hence, this Court has denied certiorari in five prior

---

[3] In its *Tamoxifen* brief, the United States identified no conflict, but stated that *Schering-Plough* "arguably" could be read not to "foreclose the possibility that a party challenging a patent settlement could rely on an ex ante view of the strength of the infringement claim." *Tamoxifen* Br. 16. As we have shown, there is no case support for that "possibility." A district court in the Eleventh Circuit recently rejected the same reading of *Schering-Plough*. *In re Androgel*, 687 F. Supp. 2d at 1377-79.

cases presenting the same issue (including the Federal Circuit's affirmance of the district court opinion at issue here).[4] These denials underscore the absence of any circuit conflict or reason to grant certiorari now. *See Miroyan v. United States*, 439 U.S. 1338, 1338-39 (1978) (Rehnquist, Circuit Justice) ("[U]nless applicants can demonstrate a conflict among the Courts of Appeals of which this Court was unaware at the time of the previous denials of certiorari, or which has developed since then, applicants' petition for certiorari will not [be granted] ....").

II. FUNDAMENTAL ANTITRUST PRINCIPLES SUPPORT THE RULE ADOPTED BELOW

A. The "Scope of The Patent" Rule Is Correct

As the Court has recognized, "the essence of a patent grant is the *right to exclude others* from profiting by the patented invention." *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980) (emphasis added); *accord Bement v. Nat'l Harrow Co.*, 186 U.S. 70, 91 (1902) ("The very object of [the patent laws] is monopoly."); 35 U.S.C. § 154. Thus, when patents are involved, "the protection of the patent laws and the coverage of the antitrust laws are not separate issues." *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1128 (D.C. Cir. 1981) (citing *Bement*, 186 U.S. at 91).

Because antitrust law recognizes the patentee's right to exclude, "the public [is] not entitled to profit

---

[4] *Cipro IV*, 129 S. Ct. 2828 (2009); *Tamoxifen*, 551 U.S. 1144 (2007); *Schering-Plough*, 548 U.S. 919 (2006); *Valley Drug*, 543 U.S. 939 (2004); *Cardizem*, 543 U.S. 939 (2004).

by competition among infringers." *See, e.g.*, *Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co.*, 154 F. 358, 364 (7th Cir. 1907). The antitrust plaintiff therefore bears the burden of showing that the "excluded" competition for which it seeks relief was lawful competition. *See, e.g.*, *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 790-92 (8th Cir. 2006) (no antitrust liability for conspiring to preclude the importation of illegal drugs); *Access Telecom, Inc. v. MCI Telecommc'ns Corp.*, 197 F.3d 694, 712 (5th Cir. 1999). As Judge Posner has explained, where a plaintiff makes no attempt to satisfy that burden, it cannot show harm to competition "since if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent." *Asahi Glass*, 289 F. Supp. 2d at 994.

In this case, Barr admitted infringement, and Petitioners do not allege that the Cipro Patent was invalid, much less that Bayer's suit against Barr was "objectively baseless." Hence, application of the scope of the patent rule is straight-forward: agreements within the exclusionary scope of the patent do not violate the antitrust laws. *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992) ("Should the restriction be found to be reasonably within the patent grant, *i.e.*, that it relates to subject matter within the scope of the patent claims, that ends the [antitrust] inquiry."); *USM Corp. v. SPS Techs., Inc.*, 694 F.2d 505, 513 (7th Cir. 1982) (antitrust liability may lie "only upon proof of an anticompetitive effect beyond that implicit in the grant of the patent"); *Studiengesellschaft*, 670 F.2d at 1128 ("[T]he conduct at issue is illegal if it threatens competition in areas other than those protected by

the patent, and is otherwise legal."); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981) ("[W]here a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger any liability under the antitrust laws.").

That Bayer made payments to Barr to settle Hatch-Waxman litigation does not change the "right to exclude" analysis. Under the statute, an ANDA filer infringes simply by filing its Paragraph IV Certification. *See* 35 U.S.C. § 271(e)(2)(A). Because the ANDA filer has not yet made any sales subjecting it to infringement damages, the generic challenger bears no risk in the ensuing litigation beyond litigation costs. *See Cipro II*, 261 F. Supp. 2d at 252. The innovator, however, faces the same invalidity challenge as it faces in any infringement suit in which the entire patent is at risk. *See Tamoxifen*, 466 F.3d at 207. Thus, as the Federal Circuit concluded, "a sizable exclusion payment from the patent holder to the generic manufacturer is not unexpected under the Hatch-Waxman Act, where the relative risks of litigation are redistributed." *Cipro IV*, 544 F.3d at 1333 n.11. Under Hatch-Waxman the innovator has everything to lose and the generic challenger has everything to gain. Settlement payments from the innovator to the generic challenger are therefore "a natural by-product of the Hatch-Waxman process." *Cipro II*, 261 F. Supp. 2d at 252; *accord Schering-Plough*, 402 F.3d at 1074-76; *Valley Drug*, 344 F.3d at 1310.

The courts below correctly applied these principles to this patent settlement, holding that such settlements incur antitrust liability only if their

effects exceed the patent's exclusionary scope *or* if there was fraud in the patent's procurement *or* if the infringement suit was objectively baseless. Because the settlement was within the scope of Bayer's patent, it excluded no more competition than the patent itself lawfully excluded.

B. The Ruling Below Does Not Conflict With This Court's Precedents

1. The "scope of the patent" rule that Judge Trager and the Second Circuit adopted is consistent with this Court's jurisprudence. Indeed, this Court's decision in *Walker Process*, 382 U.S. 172, shows the rule's propriety. *See Valley Drug*, 344 F.3d at 1307 (describing *Walker Process* as "[t]he only time the Supreme Court has addressed the circumstances under which the patent immunity from antitrust liability can be pierced.").

In *Walker Process,* defendant raised an antitrust counterclaim alleging that the patentee "obtained the patent by knowingly and willfully misrepresenting facts to the Patent Office." 382 U.S. at 177. The United States as amicus curiae argued that an infringement defendant could bring such a claim where the patent had been procured by actual fraud. Brief for the United States as Amicus Curiae at 7, *Walker Process*, 382 U.S. 172 (No. 13), 1965 WL 130091. The government stressed, however, that "[t]he case is entirely different from one in which a patent secured in good faith subsequently is held invalid, for there the intent to secure a monopoly is consonant with the purpose of the patent laws." *Id.*

This Court agreed that an antitrust claim would lie where the patentee committed fraud on the PTO.

Walker Process, 382 U.S. at 177. The Court admonished, however, that "[b]y the same token, [the patentee's] good faith would furnish a complete defense." *Id.* In his oft-cited concurrence, Justice Harlan emphasized that antitrust liability does not attach merely on the basis of patent *invalidity*:

> [T]o hold, as we do not, that private antitrust suits might also reach monopolies practiced under patents that for one reason or another may turn out to be voidable under one or more of the numerous technicalities attending the issuance of a patent, might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits. Hence, this private antitrust remedy should not be deemed available to reach § 2 monopolies carried on under a nonfraudulently procured patent.

Id. at 180 (Harlan, J., concurring).

Judge Trager and the Federal Circuit expressly relied on *Walker Process* in their *Cipro* opinions. *Cipro III*, 363 F. Supp. 2d at 530, Pet. App. 68a-69a; *Cipro IV*, 544 F.3d at 1336. Both the scope of the patent rule and its "objectively baseless" exception flow from this Court's insistence that "good faith" reliance on patent rights furnishes a "complete defense" to antitrust liability. *Walker Process*, 382 U.S. at 177. To base an antitrust claim against parties acting within the scope of a patent on anything less than a sham patent claim would

conflict with the express exclusion of private claims "show[ing] no more than invalidity of the patent." *Id.* at 179 (Harlan, J., concurring). Judge Trager correctly perceived that Petitioners' liability theories "would overstep the bright-line rule adopted by the Supreme Court in *Walker Process*, first elaborated upon by Justice Harlan in his concurrence and relied upon by the patent bar for the past forty years." *Cipro III*, 363 F. Supp. 2d at 530, Pet. App. 68a-69a.

2. Although the scope of the patent rule flows from *Walker Process*, Petitioners nonetheless claim that the rule conflicts with general statements in several of "this Court's patent cases." *See* Pet. 24. Petitioners' patent cases, however, are inapposite, as explained below.

Petitioners contend that the decision below conflicts with this Court's "repeated[] emphasi[s] that judicial testing of patent validity is essential" to secure the public interest, citing, *inter alia*, *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969). *See* Pet. 24-26. But *Lear* only considered whether a licensee could ever bring a challenge to the validity of the licensor's patent, and did not address whether the licensee could then settle that suit. If judicial testing of patent validity was essential, then all patent settlements would be unlawful. That is not the law: "Where there are legitimately conflicting [patent] claims or threatened interferences, a settlement by agreement rather than litigation, is not precluded by the [Sherman] Act." *Standard Oil*, 283 U.S. at 171.[5]

---

[5] Likewise, *Medimmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), concerned only a federal court's jurisdiction to hear a

Petitioners also contend that the scope of the patent standard ignores this Court's distinction between the substantive right to exclude and the "limited, qualified remedies" available to enforce that right. Pet. 27 (citing *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 392 (2006)). *eBay*, however, "h[e]ld only that the decision whether to grant or deny injunctive relief ... must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases." 547 U.S. at 394. The Court did not purport to limit the traditional remedy of infringement damages and said nothing about the ability to settle patent cases.

C. Petitioners' And Amici's "Policy" Arguments Are Unsupported and Unpersuasive

Petitioners urge the Court to disregard its own precedent and settled circuit law on grounds of "public policy." But the Petitioners and their amici invoke a strangely one-sided "policy" — one that assumes that consumers benefit only when a patent holder loses in court; one that assumes that consumers always prefer the short-term benefits of lower generic prices to the long-term benefits of newly discovered, life-saving drugs. As the current General Counsel of the FTC has noted, however, that argument "ignores the first principle that enforcing valid patents makes a major contribution to consumer welfare by providing the incentive for innovation. We ignore that incentive at our peril." Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements:*

---

licensee's declaratory judgment challenge to the licensed patent, not whether a declaratory judgment action could be settled.

The Need for Context and Fidelity to First Principles, 15 Fed. Cir. B.J. 617, 618 (2006).

In any event, Petitioners make many assertions of "fact" without record support, relying instead on public pronouncements from interested parties. For example, the opening paragraph of the Petition states that innovator drug companies "are today routinely — 15 to 20 agreements every year — paying generic drug manufacturers ... to delay entering the market," and that "these agreements are annually costing consumers and taxpayers billions of dollars." Pet 2. Neither statement is defensible.

First, in asserting that so-called reverse-payment settlements are ongoing and increasing, Petitioners rely not on record evidence, but on FTC annual reports of settlements filed pursuant to the 2003 amendments to Hatch-Waxman. The FTC analysis of those reports is based on an Orwellian redefinition of the term "payments" to include settlements with no cash payments at all, such as settlements with exclusive licenses.[6] In fact, since settlements have been reported to the FTC in 2004, only *five* included cash payments to the generic, and all were small amounts for "litigation" expenses.[7]

---

[6] *See* Federal Trade Commission, Agreements Filed With FTC Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2008 ("FY 2008 Report") 1 n.2 & 2, *available at* http://www.ftc.gov/os/2010/01/100113-mpdim2003rpt.pdf.

[7] *See* FY 2008 Report at 4 (one settlement); Federal Trade Commission, Agreements Filed With FTC Under the Medicare Prescription Drug Improvement Act of 2003, Summary of Agreements Filed in FY 2007 ("FY 2007 Report") 4, *available at*

Second, Petitioners' assertions regarding the social costs of settlements is based on a recent FTC "Study" whose title reflects its bias: Federal Trade Commission, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions: An FTC Staff Study (2010) *available at* www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf. Commentators have shown that the study is flawed and its central conclusion on consumer benefits "is not reliable."[8] Among other things, it compares the entry dates for different settlements without controlling for salient differences, including "the average patent life remaining" at the time of settlement.[9] Even with its flaws, the study concedes that the consumer "loss" it derives could fall from $3.5 to "$0.6 billion" (*i.e.*, over

---

http://www.ftc.gov/os/2008/05/mmaact.pdf (one settlement); Federal Trade Commission, Agreements Filed With FTC Under the Medicare Prescription Drug Improvement Act of 2003, Summary of Agreements Filed in FY 2006 ("FY 2006 Report") at 4, *available at* http://www.ftc.gov/reports/mmact/MMAreport2006.pdf (three settlements). The reports for FY 2004 and FY 2005 reflect no cash payments. The FTC has not issued an FY 2009 report.

[8] Bret Dickey et al., *A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on 'Reverse Payment' Settlements* at 2 (2010), *available at* http://newsroom.law360.com/articlefiles/186893-Analysis.pdf; *See also, e.g.*, Anjan Chatterji & Xiang Yu, *Impact of Reverse Exclusionary Settlements on Consumer Welfare: A Law and Economic Analysis*, 23 Antitrust Health Care Chronicle, July 2010, at 2, 5 (with necessary adjustments, "the [alleged] benefits in the FTC Findings are reduced to a minimum.").

[9] Dickey et al., *supra* note 8, at 3 ("Such differences would render invalid the comparison of entry delay between the two types of settlements.").

82%) if some of its (undisclosed) "assumptions," were "varied." *Id.* at 10.

Based on another FTC study, several amici recite the incorrect assertion that, "between 1992 to 2000, ... the patent owner lost 73% of the cases" filed under Hatch-Waxman. Brief Amici Curiae of 86 Professors ("Professors Br.") at 10 (discussing Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study (2002) ("FTC 2002 Study"), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf). Yet, the study refutes that claim because it shows a success rate for first-filers in all cases of just 29%. FTC 2002 Study at 14-16 (22 victories in 75 challenges). To produce a 73% "success" rate, the FTC had to reduce the number of total drug products considered, eliminating cases still pending, cases that settled, cases in which the generic withdrew its ANDA, and — critically here — cases in which the same drug patent was litigated more than once. *Id.* at 19. Thus, Bayer's three separate Cipro victories counted as only one win for a patent holder. Subsequent studies have found that the actual generic success rate is less than 50%.[10]

The flaws in Petitioners' extra-record materials show why appellate courts focus on evidence actually presented and proven in court. Whatever their merit,

---

[10] Adam Greene & D. Dewey Steadman, *Pharmaceuticals, Analyzing Litigation Success Rates*, RBC Capital Markets 1 (2010) (overall generic success rate of 48% was significantly lower in courts and before judges who saw the greatest volume of cases), *available at* http://amlawdaily.typepad.com/pharmareport.pdf; *see also* Gregory Glass, *Why Settle?*, UPDATE, Sept.-Oct. 2005, at 17-18 (generic challenger prevailed in 35% of cases brought).

Petitioners' policy arguments should be addressed to Congress, not to this Court.

III. THIS CASE IS A POOR VEHICLE TO RESOLVE THE QUESTION PRESENTED

1. a. This settlement arose under the regulatory regime in place before Congress substantially amended the Hatch-Waxman Act in 2003. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. As the Solicitor General noted in *Tamoxifen* (a pre-2003 settlement case), Congress "altered the regulatory dynamic" under which the settlement here is to be evaluated when it amended the Hatch-Waxman Act in 2003. Tamoxifen Br. at 19.

The 2003 amendments counsel against review of issues arising from a small set of settlements in an outdated regulatory context. *See* Eugene Gressman et al., Supreme Court Practice 247 (9th ed. 2007) ("If the statute upon which the controversy rests has expired or been amended in a manner that will prevent the problem from arising in the future, certiorari may be denied ....").

The 2003 amendments to Hatch-Waxman included, among other things, a new provision governing the first generic filer's right to 180 days of "exclusivity" before other generics may enter. Petitioners claimed that the exclusivity provisions created a "bottleneck" by preventing subsequent challenges to the patent after a settlement. Petitioners' argument was based on the *prior* statute's 180-day exclusivity provision, not the current provisions.

Petitioners argued in the district court that the pre-2003 statute's treatment of a "bottleneck" was central to the analysis of reverse payments. Petitioners' theory was that later entry by other generics could not remove the alleged harm of settlement payments because "[f]uture challenges" were deterred by "Defendants' manipulation of the 180-day exclusivity." Mem. of Direct Purchaser Pls.' in Opp'n to Defs.' Mots. for Summ. J., *Cipro* MDL (July 9, 2004) (Supp. App. 11a). Petitioners' co-plaintiffs also argued that the pre-2003 "bottleneck" made a reverse payment settlement "far more damaging to competition than the garden variety agreement not to compete." Indirect Purchaser Class Pls.' Mem. of Law in Opp'n to All Defs.' Mots. to Dismiss, *Cipro* MDL (May 22, 2002) (Supp. App. 6a). The commentators on whom Petitioners rely emphasize that the 180-day exclusivity period "make[s] [Hatch-Waxman] patent settlements *fundamentally different* from other patent infringement settlements."[11]

But in this case, the undisputed facts belie any "bottleneck" claim because multiple generic challenges followed the settlement. *See* Pet. App. 17a n.9.

The point for certiorari analysis is that the current statute fundamentally undermines Petitioners' reliance on the "bottleneck" theory in all cases. The

---

[11] Herbert Hovenkamp et al., IP and Antitrust § 7.4, at 7-34 (2004) (emphasis added); David Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321, 331 (2000) ("Hatch-Waxman Act [exclusivity] provides one critical feature that makes a world of difference ....").

2003 amendments introduced the term "first applicant" for purposes of exclusivity, changed the triggering mechanism, ensured that any entry under a settlement license would trigger the 180 days, and provided a series of mechanisms by which exclusivity could be forfeited. *See* 21 U.S.C. § 355(j)(5)(B)(iv), (D). In the words of a draftsperson, the 2003 amendments "ensure that the 180-day exclusivity period ... cannot be used as a bottleneck to prevent additional generic competition."[12]

The Solicitor General has advised this Court on multiple occasions that the 2003 amendments to the Hatch-Waxman Act make cases decided under the prior statute poor vehicles for certiorari: "To the extent the Court is inclined to address the validity of that type of settlement in particular, it may be preferable to do so in a case that arises under the current regulatory regime." Tamoxifen Br. at 20; *see also* Cardizem Br. at 18-19. The advice remains sound. If the Court were to grant certiorari here, it would resolve questions relating to the prior statute that are of no prospective application. Such a decision could lead to confusion under the different language of the current regime.

---

[12] 149 Cong. Rec. 31200 (2003) (Remarks of Sen. Schumer); *see also* 149 Cong. Rec. 31783 (2003) (Remarks of Sen. Kennedy) ("The Hatch-Waxman provisions in this bill are intended to prevent parking of the exclusivity."); *see generally* Natalie M. Derzko, *The Impact Of Recent Reforms Of The Hatch-Waxman Scheme On Orange Book Strategic Behavior And Pharmaceutical Innovation*, 45 IDEA 165, 245 (2005) ("In particular, the new 180-day exclusivity provision should prevent anticompetitive settlement agreements from being entered into.").

b. Congress is in the midst of considering legislation that could moot the issues in this case going forward. In the last Congress, Senator Kohl's Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009), was voted out of the Senate Judiciary Committee. The bill declared presumptively illegal "any agreement resolving or settling a patent infringement claim" in which the "ANDA filer receives anything of value." *Id.* § 3. Congressman Rush introduced the similar Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009), which the House twice included in larger bills, only to be dropped in the reconciliation process. *See, e.g.*, Supplemental Appropriations Act of 2010, H.R. 4899, 111th Cong. (2010). Senator Kohl has already introduced nearly identical legislation in the current Congress. Preserve Access to Affordable Generics Act, S. 27, 112th Cong. (2011).

2. This case is also a poor vehicle because Petitioners have not set forth the legal rule that they wish the Court to adopt. Nor have they made any attempt to show that the outcome of this case would change under a legal rule different from that applied below. While Petitioners criticize the current law, they offer no alternative rule, much less any defense of that rule. The academic amici concede that they "differ in their views on precisely what standard should be applied to judge the legality of exclusionary settlements." Professors Br. at 5.

This Court does not issue advisory opinions. *See Preiser v. Newkirk*, 422 U.S. 395, 401 (1975). Nor is the Court required to guess at the proper rule, nor to apply for the first time an analysis that no court may

have considered. *See The Monrosa v. Carbon Black Export, Inc.*, 359 U.S. 180, 184 (1959) ("Resolution here of the [issue presented] can await a day when the issue is posed less abstractly.").

3. Finally, the Petition presents a poor test case in view of the Cipro Patent's track record. The validity of Bayer's patent has been vindicated before the PTO on reexamination, in three district court challenges to judgment, and at the Federal Circuit. *See Bayer AG v. Schein Pharms., Inc.*, 301 F.3d 1306 (Fed. Cir. 2002). In fact, on the appeal of the Indirect Purchasers in this case, the Federal Circuit agreed that no fraud on the PTO had occurred. *Cipro IV*, 544 F.3d at 1341. As Judge Trager stated, "there is something anomalous about the notion that plaintiffs could collect treble damages for settlement of a litigation involving a patent that has been subsequently upheld by the Federal Circuit." *Cipro III*, 363 F. Supp. 2d at 530 n.14, Pet. App. 67a n.14. Petitioners make no argument that any test based on the "strength" or possible invalidity of the patent would change the result in this case. *See* Pet. 14-15, 21-22. Thus, Judge Trager concluded, "a *post hoc* assessment of the validity of the ciprofloxacin patent would likely do plaintiffs little good." *Cipro III*, 363 F. Supp. 2d at 530, Pet. App. 70a.

CONCLUSION

The Court should deny the Petition as it did in this case on certiorari to the Federal Circuit.

Respectfully submitted,

PHILLIP A. PROGER
KEVIN D. MCDONALD
LAWRENCE D. ROSENBERG
CHRISTOPHER S. PERRY
MARK R. LENTZ
JONES DAY
51 Louisiana Ave., N.W.
Washington, D.C. 20001
(202) 879-3939

February 4, 2011

FRED H. BARTLIT, JR.
Counsel of Record
PETER B. BENSINGER, JR.
MICHAEL J. VALAIK
PAUL J. SKIERMONT
BARTLIT BECK HERMAN
PALENCHAR & SCOTT LLP
54 West Hubbard St.
Suite 300
Chicago, IL 60654
(312) 494-4400
fred.bartlit@bartlit-beck.com

Counsel for Respondents Bayer AG & Bayer Corp.

SUPPLEMENTAL APPENDIX*

* The materials excerpted in this Supplemental Appendix were originally filed under seal in the district court pursuant to a stipulated protective order. However, by subsequent agreement, these excerpts are no longer under seal, and the excerpts do not refer to any document that remains under seal.

APPENDIX A

FILED UNDER SEAL

This document contains reference to highly confidential and confidential material subject to Protective Order

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

IN RE CIPROFLOXACIN HYDROCHLORIDE ANTITRUST LITIGATION	)	Master File No. 1:00-MD-1383
This Document Relates to:	)	Hon. David G. Trager, U.S.D.J.
	)	Hon. Steven M. Gold, U.S.M.J.
ALL ACTIONS	)	

AFFIDAVIT OF RAYMOND RASIMAS

County of New Haven)
) ss: West Haven, CT
State of Connecticut)

Raymond Rasimas, being sworn, deposes and says:

1. My name is Raymond Rasimas. I attest to the following facts based on personal knowledge.

2. My current title is Senior Financial Specialist. I am primarily responsible for providing financial

analysis to management; ensuring and reporting Bayer's compliance with its 3rd party contracts; and interfacing with all functional areas of Bayer in support of the collection of financial data.

3. In January 1997, Bayer paid to the Barr Escrow Account a total of $49.1 million. The payment represented 6.2% of Bayer's 1997 U.S. gross sales of oral Cipro tablets ($787.1 million). From 1997 through the end of 2003 when Bayer ceased payments, Bayer's settlement payments totaled $398.1 million, representing 6.5% of Bayer's U.S. gross sales of oral Cipro tablets for the period ($6.1 billion).

I declare under penalty of perjury that the foregoing statements and information are true and correct.

/s/ Raymond J. Rasimas
Raymond Rasimas

Sworn to before me
this 26th day of May 2004

/s/ Elaine Porter
Notary Public

Elaine Porter
Notary Public
My Commission Expires June 30, 2006

CONTAINS CONFIDENTIAL INFORMATION
SUBJECT TO COURT ORDER

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

IN RE CIPROFLOXACIN HYDROCHLORIDE ANTITRUST LITIGATION	Master File No. 1:00-MDL-1383 Hon. David G. Trager, USDJ Hon. Steven M. Gold, USMJ
THIS DOCUMENT RELATES TO: ALL INDIRECT PURCHASER CLASS CASES	

INDIRECT PURCHASER CLASS PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO ALL DEFENDANTS' MOTIONS TO DISMISS THE INDIRECT PURCHASER CLASS PLAINTIFFS' COMPLAINTS

FILED UNDER SEAL PURSUANT TO STIPULATED PROTECTIVE ORDER GOVERNING CONFIDENTIAL MATERIAL DATED JULY 9, 2001

* * *

CONTAINS CONFIDENTIAL INFORMATION
SUBJECT TO COURT ORDER

A. A Combination Of The Pioneer Drug Patent Holder And The First ANDA(IV) Filer Can Result In An Unreasonable Restraint Of Trade.

Holders of valid patents are liable for antitrust violations when they combine with horizontal competitors to exclude competition, as have Bayer, Barr, HMR and Rugby. *See, e.g., Andrx*, 256 F.3d at 812 n.15 ("[E]ven a patent-right holder is not immune from antitrust liability."); *Terazosin I*, 164 F. Supp. 2d at 1354 ("Abbott's efforts to parlay its patents into agreements with its competitors to limit the domestic sale of generic Terazosin hydrochloride drugs is exactly 'the type of commercial activity that has traditionally had its validity determined by the antitrust laws.'") (citations omitted); *see also United States v. Microsoft Corp.*, 253 F.3d 34, 63 (D.C. Cir.), *cert. denied*, 122 S. Ct. 350 (2001) ("'Intellectual property rights do not confer a privilege to violate the antitrust laws.'") (citation omitted). In *United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963), the Supreme Court held that competitors can violate the antitrust laws when they "pool" their patent rights for exclusionary purposes. *See id.* at 194.

> It is well settled that beyond the limited monopoly which is granted, the arrangements by which the patent is utilized are subject to the general law, and "it is equally well settled that the possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of its patent monopoly. By aggregating patents in one control, the holder of the patents cannot escape the prohibitions of the Sherman Act."

CONTAINS CONFIDENTIAL INFORMATION
SUBJECT TO COURT ORDER

> That Act imposes strict limitations on the concerted activities in which patent owners may lawfully engage, and those limitations have been exceeded in this case.

Id. at 196-97 (citations and quote marks omitted); *see also United States v. New Wrinkle, Inc.*, 342 U.S. 371, 379 (1952).

The Exclusivity Period under the Hatch-Waxman Act is analogous to a patent in that it provides government-sanctioned insulation from generic competition for 180 days in order to reward and encourage conduct that is in the public interest. *Andrx*, 256 F.3d at 813 n.15. Just as a valid patent results in a carefully tailored monopoly designed to reward investment and innovation, the Exclusivity Period incentivizes generic companies to develop around and challenge pioneer companies' patents. Patents and the Exclusivity Period are narrowly construed exceptions to the general rule against monopolies and the right to a free and open market. *Andrx*, 256 F.3d at 813 n.15. Under the language of the Hatch-Waxman Act, the FDA has the authority to grant final approval to an ANDA(IV) after the 30-month stay expires, thus enabling the applicant to bring its product to the market despite the pendency of patent litigation. *See Ciprofloxacin*, 166 F. Supp. 2d at 744; Cpt. ¶ 42. Commercial marketing following FDA approval will "trigger" the Exclusivity Period, which will then open the door, 180 days later, to FDA approval for other generic manufacturers to enter the market.

The Hatch-Waxman Act necessarily contemplates that the patent holder and the first ANDA(IV) filer

CONTAINS CONFIDENTIAL INFORMATION
SUBJECT TO COURT ORDER

must be adversaries, with the latter fighting to get its competitive product to the market as soon as possible to reap the benefits of 180 days as the exclusive generic. These rights are so inherently incompatible,[11] the statutory scheme does not contemplate a partnership between these would-be competitors by which the first ANDA(IV) filer withholds its product from the market (thereby keeping all generic competition at bay) in exchange for a share of the monopoly rents from the pioneer manufacturer. *See Andrx*, 256 F.3d at 809 ("[T]he statutory scheme does not envision the first applicant's agreeing with the patent holder of the pioneer drug to delay the start of the 180-day exclusivity period."); *see also Cardizem I*, 105 F. Supp. 2d at 657-58; *Biovail*, 49 F. Supp. 2d at 767-68. As such an agreement precludes new entry by other potential competitors, it is far more damaging to competition than the garden variety agreement not to compete. *See Andrx*, 256 F.3d at 814 ("Antitrust law looks at entry into the market as one mechanism to limit and deter exploitation of market power by those who may temporarily possess it."); Balto, 55 Food & Drug L. J. at 332 ("Agreements that restrict new entry therefore are viewed with great concern.").

* * *

[11] It is inconceivable, for example, that the same entity could be both the pioneer patent holder and the first ANDA(IV) filer – *i.e.*, a pharmaceutical company (either directly or through a subsidiary) could not file an ANDA(IV) and challenge the validity of its own patent so as to claim the Exclusivity Period on top of its patent rights.

CONTAINS CONFIDENTIAL INFORMATION
SUBJECT TO COURT ORDER

APPENDIX C

CONFIDENTIAL
FILED UNDER SEAL

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

IN RE CIPROFLOXACIN HYDROCHLORIDE ANTITRUST LITIGATION	Master File No. 100-MDL-1383 Honorable David G. Trager, U.S.D.J. Honorable Steven M. Gold, U.S.M.J.
THIS DOCUMENT RELATES TO: Louisiana Wholesale Drug Co. (No. 00-5191) CVS Meridian, Inc. (No. 00-7951)	

MEMORANDUM OF DIRECT PURCHASER PLAINTIFFS IN OPPOSITION TO DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT [CORRECTED VERSION]

Bruce E. Gerstein
Barry S. Taus
Steve D. Shadowen
Monica L. Rebuck

CONTAINS CONFIDENTIAL INFORMATION
SUBJECT TO COURT ORDER

Jan Bartelli
Garwin, Bronzaft, Gerstein & Fisher, LLP
1501 Broadway, Suite 1416
New York, NY 10036
(212) 398-0055

Lead Counsel, Direct Purchaser Class Cases

HANGLEY ARONCHICK SEGAL & PUDLIN
30 North Third Street – Suite 700
Harrisburg, PA 17101-1701
(717) 364-1030

Attorneys for Plaintiffs CVS Pharmacy, Inc. and Rite Aid Corporation

Dated: July 9, 2004

* * *

F. Defendants' Proposed Rule Would Result in Significant Consumer Harm.

It is Defendants' proposed rule, not Plaintiffs', that would have far-reaching and dire consequences. Defendants assert that there is no harm to consumers from permitting pioneers to make exclusion payments because consumers can prevail on an antitrust claim in those instances in which the pioneer obtained the patent by fraud or enforced it with no reasonable basis to believe that it was enforceable. (Bayer Br. at 17-19.) Defendants' assertion that antitrust liability should be limited to those circumstances highlights the extreme nature of their proposed rule.

If exclusion payments are allowed, then litigants' economic incentive will be to settle *all* patent disputes that *can* be settled with exclusion payments rather than licenses. (Tab 17 at ¶ 48.) Defendants' own expert agrees with this assessment. (Tab 32 at

CONTAINS CONFIDENTIAL INFORMATION
SUBJECT TO COURT ORDER

88-89.) The result would be the near complete elimination of the vital function that courts play in policing patent validity. (Tab 17 at ¶ 49.)

Defendants try to soften these damning facts by asserting that consumers might be able to state an antitrust claim when the pioneer has entered into a series of exclusion payment settlements. (Bayer Br. at 18) And Defendants attempt to distinguish this case from *Cardizem* and *Terazosin* on the ground that the agreement here allegedly did not have the effect of barring other generic competitors from the market. (Generics Br. at 18-19) Defendants are wrong as a matter of both law and fact.

Antitrust liability attaches to a single act of anticompetitive conduct -- a series of such anticompetitive actions is not required. *See, e.g., Walker Process Equip., Inc. v. Food Machinery & Chem. Corp.*, 382 U.S. 172 (1965) (a single instance of enforcing a fraudulently procured patent can violate Section 2 of the Sherman Act). Moreover, pioneers will in fact make exclusion payments only when it is worthwhile for them to do so -- only when the retained monopoly made possible by the exclusion payment exceeds the amount of the exclusion payment. Thus, the fact that a pioneer has made an exclusion payment to a single potential competitor proves that a payment to that single competitor was all that was necessary to harm consumers. (Tab 17 at ¶ 27, 52).

This case, and the comparison of its facts to those in *Cardizem* and *Terazosin*, illustrate this principle. When Bayer agreed to make the exclusion payments to Barr and HMR/Rugby, no other generic

CONTAINS CONFIDENTIAL INFORMATION
SUBJECT TO COURT ORDER

manufacturer had yet filed an ANDA IV. (Tab 30 at 247.) Under the law as it existed at that time, a subsequently-filing generic challenger would be subject to the automatic 30-month Hatch-Waxman stay. Allowing for time for a second challenger to prepare and file an ANDA IV and then to wait out the 30-month stay, Bayer estimated that the exclusion payment settlement would permit it to be free from *all* generic competition -- not just competition from Barr and HMR/Rugby -- until at least January 2000. (Tab 43H at BCP 4610057.)

Absent the exclusion payment, Bayer estimated that the Federal Circuit would render a decision in the Bayer/Barr litigation by January 1999. (Tab 43H at BCP 4610057.) Barr estimated such a decision would occur by January 1998. (Tab 24 at 227.) Thus, the exclusion payment bought Bayer the absence of *all* generic competition from January 1998 or 1999 to January 2000 -- between 12 to 24 months. (Tab 43H at at BCP 4610057.) That period of exclusion actually exceeds the period involved in *Cardizem* (11 months) and is comparable to that involved in *Terazosin* (16 months). *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 632 (E.D. Mich. 2000); *In re Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 2d 1340, 1347 (S.D. Fla. 2000).

The exclusion payments also bought Bayer a more favorable forum in which to have its patent tested. Bayer's strategy was to settle the Barr challenge and then submit the '444 patent for reexamination at the PTO. Bayer AG's Chairman admitted that the purpose of submitting the patent for reexamination was to *ward off future challenges in the court*

CONTAINS CONFIDENTIAL INFORMATION
SUBJECT TO COURT ORDER

system -- Bayer believed that if it were successful in the reexamination, no other generic manufacturer would challenge the patent in court. (Tab 40 at 69.)

It was in Bayer's economic interest to have the patent's validity tested in the PTO rather than in the courts. (Tab 40 at 68.) A PTO reexamination is an *ex parte* proceeding in which, among other things, the issue of inequitable conduct -- one of the principal arguments raised by Barr -- cannot even be considered. (Tab 17 at ¶ 61.) Bayer was obviously aware of that key fact. (Tab 30 at 166-67.) The PTO is in fact a far more favorable forum for patent holders than are federal courts. Federal courts find 46% of all litigated patents to be invalid. (Tab 17 at ¶ 61 & n.107.) On reexamination the PTO finds only 10% of patents to be invalid. (*Id.*) Bayer in fact concluded that its chances of a favorable decision were substantially greater in the PTO than in the courts. (*Id.* at ¶ 60.)

Finally, Bayer's prediction that its settlement with Barr would ward off future court challenges turned out to be right. Future challenges were not deterred by the PTO ruling, however, but by the extra time that the settlement bought and by the Defendants' manipulation of the 180-day exclusivity.

Before Defendants entered into their unlawful Agreement, another generic manufacturer, Mylan, was preparing to file an ANDA IV. (Tab 38 at 52.) If Barr had not settled the patent litigation and had succeeded in having the '444 patent invalidated, Mylan could have filed its ANDA IV application and had FDA approval to enter the market immediately

CONTAINS CONFIDENTIAL INFORMATION
SUBJECT TO COURT ORDER

upon the expiration of Barr's 180-day exclusivity in or about June 1998. (Tab 16 at 26 n. 53.)

The Defendants' agreement affected the timing of Mylan's filing its ANDA IV application in two ways. First, a generic challenger that is not the first-filer will rationally try to "free-ride" on the legal expenses being incurred by the first-filer. (Tab 17 at ¶ 27.) Once Barr,. the first-filer, settled there was some delay while Mylan and the other potential challengers got "up to speed" in the preparation of their patent defenses in earnest. (*Id.*)

Second, at the time of the unlawful agreement, the FDA law was unclear as to whether a first-filer that settled the patent litigation and amended its certification from a Paragraph IV to a Paragraph III would forfeit its 180-day exclusivity. (Tab 17 at p. 15 n.43; *see also Cipro II* at 242.)[28] What *is clear* is that Barr told Bayer during the settlement negotiations that Barr in fact intended to assert its continued right to the 180-day exclusivity. (Tab 42 at 172.) It is also clear that the Defendants collectively maximized Barr's chances of successfully claiming the 180-day exclusivity -- the Defendants expressly provided in the Agreement that, in the event that another generic manufacturer succeeded in invalidating the '444 patent, Barr could *re-amend its*

---

[28] In *Cipro II* the Court held, on Plaintiffs' motion for partial summary judgment, that Plaintiffs had failed to establish their claim regarding the 180-day exclusivity *as a matter of law*. In opposition to the Defendants' motion, we are establishing *as a matter of fact* that the purpose and effect of Defendants' settlement agreement was to deter or delay subsequent challenges to the patent.

CONTAINS CONFIDENTIAL INFORMATION
SUBJECT TO COURT ORDER

ANDA certification from a Paragraph III back to a Paragraph IV. (Tab 42A at ¶5.) Obviously, it was in the economic interest of both Barr and Bayer for Barr to succeed in claiming the 180-day exclusivity.

These circumstances in fact delayed Mylan in the filing of its ANDA IV application. Mylan "[did] not see any chance to go ahead with the product with their legal understanding of the Waxman-Hatch exclusivity." (Tab 28.) Mylan finally filed its application in August 1999, immediately after the FDA proposed a new rule that a voluntary change in patent certification from a Paragraph IV to a Paragraph III results in the forfeiture of the 180-day exclusivity. (Tab 38 at 110; 64 Fed. Reg. 42,873 8/8/99.) Mylan has acknowledged that the Defendants' Agreeement "affected the timing of our development." (Tab 38B & 38C at § IV(2); Tab 38 at 96.)

By the time Mylan filed its application in August 1999, there were less than 4 years remaining in the patent term. Mylan could reasonably expect that litigation of an average Hatch-Waxman litigation would take at least 37 months, through a court of appeals decision. FTC, *Generic Drug Entry Prior to Patent Expiration*, iii (July 2002) *available at* http://www.ftc.gov/os/2002/07/genericdrug_study.pdf. (Tab 47).

As acknowledged by Barr's own patent counsel, one of the strongest arguments against the '444 patent was Bayer's inequitable conduct in procuring that patent. (*See* Tab 29 at 170-71.) Faced with a fast-approaching expiration of the '444 patent, Mylan "reluctantly" dropped its inequitable conduct defense.

CONTAINS CONFIDENTIAL INFORMATION
SUBJECT TO COURT ORDER

(Tab 38D at BCP 1941110.) As Mylan recognized, inequitable conduct "is the type of defense [that is] very focused on issues of intent and materiality of these different references, so you're looking at, presumably, a pretty long road to trial." (Tab 38 at 143-45.) Mylan dropped this defense in order to "present a clear issue of law to the district court and to the federal circuit so that the case could come to a resolution" before the patent would expire. (Tab 38 at 133-34.) Thus, as a result of the Defendants' Agreement and their manipulation of the 180-day exclusivity, one of the best arguments for the unenforceability of the '444 patent remains unadjudicated to this day.

Supreme Court, U.S.
FILED
FEB 16 2011
OFFICE OF THE CLERK

No. 10-762

IN THE

Supreme Court of the United States

LOUISIANA WHOLESALE DRUG CO., INC., CVS PHARMACY, INC., RITE AID CORPORATION, ARTHUR'S DRUG STORE, INC.,

Petitioners,

v.

BAYER AG, BAYER CORP., formerly doing business as Miles Inc., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., WATSON PHARMACEUTICALS, INC., BARR LABORATORIES, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

REPLY BRIEF

BRUCE E. GERSTEIN
GARWIN GERSTEIN & FISHER LLP
1501 Broadway, Suite 1416
New York, NY 10036
(212) 398-0055

DAVID F. SORENSEN
BERGER & MONTAGUE, P.C.
1622 Locust Street
Philadelphia, PA 19103
(215) 875-3000

Counsel for Petitioner Louisiana Wholesale Drug Co., Inc.

STEVE D. SHADOWEN
Counsel of Record
MONICA L. REBUCK
HANGLEY ARONCHICK SEGAL & PUDLIN
30 N. Third Street, Suite 700
Harrisburg, PA 17101
(717) 364-1030
sshadowen@hangley.com

Counsel for Petitioners CVS Pharmacy, Inc. and Rite Aid Corporation

TIMOTHY D. BATTIN
STRAUS & BOIES, LLP
4041 University Drive
Fairfax, VA 22030
(703) 764-8700

Counsel for Petitioner Arthur's Drug Store, Inc.

234669

TABLE OF CONTENTS

	Page
TABLE OF CONTENTS	i
TABLE OF CITED AUTHORITIES	ii
INTRODUCTION	1
I. The Courts Are Divided Over the Proper Standard for Evaluating Whether Exclusion Payments Are Anticompetitive.	2
II. The Second Circuit's Standard Conflicts with This Court's Precedents.	6
III. This Case Is the Right Vehicle to Resolve This Recurring Issue of Enormous Public Importance.	10
CONCLUSION	12

TABLE OF CITED AUTHORITIES

Page

CASES

Andrx Pharm. Inc. v. Biovail Corp. Int'l,
256 F.3d 799 (D.C. Cir. 2001) 4

Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.,
402 U.S. 313 (1971) 7, 8

In re Cardizem CD Antitrust Litig.,
332 F.3d 896 (6th Cir. 2003) 3, 4

In re K-Dur Antitrust Litig.,
No. 01-1652, 2009 WL 508869
(D.N.J. Feb. 6, 2009) 4

In re Terazosin Hydrochloride Antitrust Litig.,
352 F. Supp. 2d 1279 (S.D. Fla. 2005) 5, 6

King Drug Co. v. Cephalon, Inc.,
702 F. Supp. 2d 514 (E.D. Pa. 2010) 5

Monell v. Dep't of Social Services,
436 U.S. 658 (1978) 11

State Oil Co. v. Khan,
522 U.S. 3 (1997) 11

United States v. Glaxo Group Ltd.,
410 U.S. 52 (1973) 8

Cited Authorities

Page

Valley Drug Co. v. Geneva Pharms., Inc.,
344 F.3d 1294 (11th Cir. 2003) 4, 5, 6

Walker Process Equip., Inc. v.
Ford Mach. & Chem. Corp.,
382 U.S. 172 (1965) 9

OTHER AUTHORITIES

I Herbert Hovenkamp, et al., IP AND ANTITRUST:
An Analysis of Antitrust Principles Applied to Intellectual Property Law § 15.3 (2d ed. 2010 Supp.) 3, 5-7, 10

The Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706, Before H. Comm. on Energy and Commerce,
111th Cong. (Mar. 31, 2009) 11

INTRODUCTION

Petitioners alleged below that, absent the $398 million exclusion payments, the patent case would either have: (1) been settled by Bayer granting Barr an early-entry license; or (2) not been settled, and Barr would have won and entered the market. Pet. App. 18a. Under the "patent strength" antitrust standard applied by the Sixth Circuit, D.C. Circuit, and the FTC, evidence that Bayer paid Barr $398 million would have satisfied Petitioners' initial burden under the rule of reason, and, in the Sixth Circuit, would have rendered the exclusion payments per se unlawful. Under the Eleventh Circuit's "patent relitigation" standard, Petitioners could have prevailed by proving that Barr likely would have won the patent case.[1] Under the Second Circuit standard, however, summary judgment was entered against Petitioners because they did not allege that Bayer procured the patent by fraud or that the underlying patent litigation was a sham.

Respondents' argument that there is no split among the circuits relies on tendentious readings of the cases. Their arguments on patent and antitrust law depend on extreme and unsupportable propositions – that "there is no federal 'policy in favor of judicial examination of

1. Bayer misleadingly asserts that Petitioners do not contend that the patent "was invalid." Bayer Br. 22. Petitioners have consistently asserted that, if the patent case had not settled, Barr would have won by proving the patent invalid or unenforceable. Respondents also mislead by asserting that the PTO and the courts subsequently found the patent valid. *Id.* at 6; Barr Br. 3-4. The PTO lacks jurisdiction to decide inequitable conduct defenses, and subsequent challengers did not have time to litigate the fact-intensive defenses that Barr had intended to pursue at trial. *See* Pet. Br. 27; Bayer Supp. App. 11a, 13a-14a. The best defenses to the patent have never been adjudicated.

patent validity'" (Barr Br. 18) and that competitors' joint conduct in excluding competition by private contract should enjoy the same scope of antitrust immunity as a patentee's unilateral conduct in asking government to restrain competition (Bayer Br. 24-26).

I. The Courts Are Divided Over the Proper Standard for Evaluating Whether Exclusion Payments Are Anticompetitive.

Concerning the split between the Second and Eleventh Circuits, the Solicitor General has previously advised this Court that:

> [T]he Eleventh Circuit (unlike the [Second Circuit]) did not purport to hold that proof of "sham" or "objectively baseless" litigation is a prerequisite to antitrust liability.... [or] foreclose the possibility that a party challenging a patent settlement could rely on an ex ante view of the strength of the infringement claim in contending that the settlement was invalid ... [T]herefore, the Eleventh Circuit's standard might permit imposition of antitrust liability in some cases in which the [Second Circuit] standard ... would not.

United States Amicus Curiae Br., *Joblove v. Barr Labs., Inc.*, *No.* 06-830 ["*Tamoxifen Br.*"] at 16 (S. Ct. May 2007).[2]

---

2. The Solicitor General urged the Court to deny certiorari in *Tamoxifen* because the claims there "appear[ed] to be moot," *Tamoxifen Br.* at 17, as were the claims of the plaintiffs in the Federal Circuit's *Ciprofloxacin* case, Pet. Br. 33.

The circuit split prevents practitioners from giving clients reliable advice. *See, e.g.*, I Herbert Hovenkamp, et al., IP AND ANTITRUST: *An Analysis of Antitrust Principles Applied to Intellectual Property Law* § 15.3, at 15-29 (2d ed. 2010 Supp.) ["Hovenkamp, IP AND ANTITRUST"] (noting the circuits' "widely different outcomes, ranging from per se illegality to per se legality and including various sorts of rule of reason analysis in between"); Br. Amici Curiae of the States of California, et al., at 3 ("The Attorneys General need guidance as to the legality of reverse payment agreements")[3]; Br. Amici Curiae of 86... Professors, at 6 (three-way split precludes reliable advice). The Solicitor General previously identified *this case* as a possible vehicle for the Court to resolve the exclusion payment issue. United States Amicus Curiae Br., *Federal Trade Comm'n v. Schering-Plough Corp.*, No. 05-273 at 1, 20 (S. Ct. May 2006).

Respondents erroneously deny that there is any circuit split:

Sixth Circuit/D.C. Circuit/FTC. Relying on a single footnote, Respondents assert that the Sixth Circuit condemned the agreement in *Cardizem* because one clause would have precluded the generic from entering even with a hypothetical, concededly non-infringing product. Bayer Br. 15; Barr Br. 12. The Sixth Circuit's analysis, however, hinged on the real competitive effects of blocking entry of a real product whose infringement was contested in the patent litigation, not the hypothetical effects of blocking a hypothetical product. *See In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 902, 907-08 (6th Cir. 2003).

3. Unless otherwise noted, citations to amicus briefs are to those filed with the Court in this case.

The D.C. Circuit applied the patent strength standard to the same agreement without even pausing to refer to the hypothetical-product clause on which Respondents rely. *Andrx Pharm. Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809, 813 (D.C. Cir. 2001). The FTC also applies the patent strength standard without regard to the presence or absence of such a clause.

Just as tellingly, other courts have refused to apply the patent strength standard despite the presence of hypothetical-product clauses at least as broad as the one in *Cardizem*: the Eleventh Circuit rejected *Cardizem* and applied a patent relitigation standard, *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003), and a Third Circuit district court rejected *Cardizem* and adopted the Second Circuit standard, *In re K-Dur Antitrust Litig.*, No. 01-1652, 2009 WL 508869, at *28 (D.N.J. Feb. 6, 2009).[4] Respondents cannot distinguish *Cardizem* based on a distinction that is honored by neither the courts that apply the patent strength standard nor those that reject it.

Eleventh Circuit. The Eleventh Circuit in *Valley Drug* directed the district court on remand to determine the "scope of the exclusionary potential of the patent" by comparing the agreement to "the protections afforded

4. The clause in *Cardizem* precluded entry of the challenged generic product "or other bioequivalent or generic version of Cardizem CD," *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682, 696 (E.D. Mich. 2000); the *Valley Drug* clause precluded entry of the challenged generic product or "any pharmaceutical product containing any form of terazosin hydrochloride," 344 F.3d at 1300; and the *K-Dur* clause precluded entry of the challenged generic product or "any potassium chloride product," 2009 WL 508869, at *10.

by the preliminary injunction and stay mechanisms and considered in light of the likelihood of [the brand's] obtaining such protections." 344 F.3d at 1312. Because the court used the "exclusionary scope" language later used by the Second Circuit, Respondents assert that the Eleventh Circuit must have meant to adopt the fraud/sham standard rather than the patent relitigation standard. *See* Bayer Br. 18; Barr Br. 16.

On remand in *Valley Drug*, however, the district court unambiguously applied the patent relitigation standard, focusing on "the likely outcomes of the patent litigation that was pending at the time the parties entered into the Agreement.... By exploring the likely outcomes of the litigation, the Court can delineate the protections afforded by the patent...." *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1299 (S.D. Fla. 2005). Expressly holding that Abbott's infringement claim was not a sham, the court nevertheless held the exclusion payments unlawful because the patent claim "was weak and unlikely to result in a District Court finding that the '207 patent was valid, [and] it follows that Abbott was unlikely to obtain a preliminary injunction to keep Geneva off the market through appellate resolution...." *Id.* at 1306.

The Eleventh Circuit standard is read the same way by the United States, *see supra* at 2, by other courts, *e.g.*, *King Drug Co. v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 534 (E.D. Pa. 2010) (relying on *Valley Drug*, finding invalidity and non-infringement allegations sufficient to show exclusion payments "exceeded the exclusionary power of [a] patent because similar protection could not have been obtained by enforcing the patent through litigation"), and by leading commentators, *e.g.*, Hovenkamp, IP AND

ANTITRUST, at 15-36 (under *Valley Drug* "the legality of the settlement agreement depend[s] on whether the patentee would in fact have won the underlying patent suit").

Respondents assert that all of these authorities are wrong, pointing to *Valley Drug*'s statement that plaintiffs cannot impose antitrust liability "merely because the patent is subsequently declared invalid." *See* 344 F.3d at 1308; Bayer Br. 18. In the underlying patent litigation, the patent was ultimately found invalid, and this language noted only that such a subsequent finding cannot justify antitrust liability because an agreement must be judged as of the time it was made; the district court was to determine the likelihood of a preliminary injunction without the benefit of hindsight. 344 F.3d at 1306. *See also In re Terazosin*, 352 F. Supp. 2d at 1302; Hovenkamp, IP AND ANTITRUST, at 15-35.

II. The Second Circuit's Standard Conflicts with This Court's Precedents.

Patent Cases. Respondents assert that, absent fraud or sham litigation, this Court's patent cases permit litigants to settle "on whatever terms they see fit" as long as the exclusion does not exceed the patent's temporal or subject matter scope. Barr Br. 18; Bayer Br. 23-24. Thus, a patentee with only a colorable claim -- say, only a 20% chance of winning -- can pay the alleged infringer (including an amount greater than he could have made by winning the patent case) to confess validity and infringement and stay out of the market until the patent expires.

Spanning two administrations, however, the United States has made clear that the Second Circuit's standard is

"insufficiently stringent" and "erroneous." *Tamoxifen Br.* at 8, 16. Courts should "at a minimum ... take into account the relative likelihood of success of the parties' claims, viewed ex ante." *Id.* at 12. The circuit's standard "offers no protection to the public interest in eliminating undeserved patents." United States Br., *In re Ciprofloxacin*, No. 05-2852 at 15 (2d Cir. July 6, 2009). The standard "is without justification in competition or innovation policy" and "improperly undermines the balance Congress struck in the Patent Act between the public interest in encouraging innovation and the public interest in competition." United States Br. Amicus Curiae, *In re Ciprofloxacin*, No. 05-2852 at 5, 3 (2d Cir. June 3, 2010); *see also* Br. Amicus Curiae of American Antitrust Institute, at 14 (standard "confuse[s] the right of a patentee to exclude others ... with a supposed right to pay potential competitors not to test the validity of a patent").

This Court in *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 344 (1971), made clear that the public interest in patents gives rise to two lines of cases -- one requiring that exclusion not exceed the patent's subject matter and temporal scope, and another "encourag[ing] authoritative testing of patent validity." *See also* Br. Amici Curiae of Consumer Fed. of America, et al., at 23 ("if the patent is not valid, it does not have any scope"); Hovenkamp, IP AND ANTITRUST, at 15-49 ("The legitimate exclusion value of a pharmaceutical patent is the power it actually confers over competition, which is in turn a function of the scope of the patent and its chance of being held valid."). Respondents' opposition is founded on the contention that this second line of authority does not exist, that "there is no federal 'policy in favor of judicial examination of patent validity.'" Barr Br. 18.

Respondents are wrong. See the cases cited in Petitioners' Brief at 24-26, more cases cited in *Blonder-Tongue Labs.*, 402 U.S. at 344-45, and yet more cases cited in *United States v. Glaxo Group Ltd.*, 410 U.S. 52, 57 (1973). Indeed, recently the generic manufacturers successfully urged this Court to decide whether the "clear and convincing evidence" standard applies to the defense of patent invalidity. Br. Amici Curiae of Teva Pharmaceuticals USA, Inc., et al., *Microsoft Corp. v. i4i L.P.*, No. 10-290 (S. Ct. Sept. 29, 2010), *cert. granted* (Nov. 29, 2010). The generics' trade association correctly asserted that "the public have a vital interest" in "having ... invalidity challenges fairly and realistically assessed under appropriate standards," thus "ensuring that invalid patents are not used to stifle legitimate innovation and new products." *Id.* at 4. This vital public interest in fair and realistic invalidity challenges is not served when generics share patentees' monopoly profits in exchange for forgoing those challenges and staying out of the market.

Nor do Respondents deny that the Second Circuit standard conflicts with the Hatch-Waxman Act's incentives for generics to enter the market through patent litigation and the Act's denial of automatic exclusion of generics after 30 months. *See* Pet. Br. 29-30; *see also* Br. Amicus Curiae of AARP, at 11 (if Second Circuit standard prevails, "the patent-challenge provisions of the Hatch-Waxman Act would be eviscerated, and American consumers would be left to pay the price"). Respondents instead assert that the Act alters the traditional risks incurred by infringers in patent litigation, and that these altered risks make a patentee's payments to the alleged infringer a "natural by-product" of the Act. Bayer Br. 23. Both parts of Respondents' argument are wrong. The

Act does not redistribute the traditional patent-litigation risks, because the patentee can choose to either invoke the automatic 30-month stay or decline it and assert a traditional patent claim for damages. *See* Pet. Br. 28 n.10. Even when the patentee chooses the 30-month stay rather than the damage claim and its resulting settlement leverage, nothing in the Act justifies a payment from the patentee to the generic. Litigants can -- and, before the *Tamoxifen* decision, did -- routinely settle Hatch-Waxman cases with early-entry licenses rather than exclusion payments. *See* Pet. App. 33a. The Act intentionally increased the incentives for generic entry. Pet. Br. 28. When Respondents reacted to the statutory opening of the market by agreeing not to compete, the courts should have subjected that conduct to intense antitrust scrutiny, not excused it as "natural."

Antitrust Law. Respondents concede that the Second Circuit standard is built on *Walker Process Equip., Inc. v. Ford Mach. & Chem. Corp.*, 382 U.S. 172 (1965). Bayer Br. 24-25; Barr Br. 21. Petitioners demonstrated at length that *Walker Process* provides antitrust immunity only for a patentee's unilateral conduct in asking the government to restrain competition. Pet. Br. 31-33. The United States agrees: "The court of appeals primarily erred by focusing on whether the underlying patent infringement claim was 'objectively baseless' – a standard typically used in determining whether a defendant is entitled to antitrust immunity under the *Noerr-Pennington* doctrine." *Tamoxifen Br.* at 13. Respondents have no answer, offering a mere assertion that *Walker Process* somehow immunizes "parties" who jointly restrain competition through private agreement. Bayer Br. 25.

Lastly, Respondents' antitrust analysis hinges on their insistence that there is no competitive difference between exclusion payment settlements and licensed entry settlements. *Id.* at 26; Barr Br. 18. Petitioners demonstrated, however, that exclusion payment settlements result in exclusion rather than entry; are determined by the sharing of monopoly profits rather than the patent's strength; sever the connection between the generic's interests and those of consumers; and deliver no benefits to consumers. Licensed entry settlements, in contrast, result in entry of the generic; are determined solely by the patent's strength; preserve the connection between the generic entrant's interests and those of consumers; and deliver to consumers the risk-adjusted benefits of the patent litigation. *See* Pet. Br. 10; *see also* Hovenkamp, IP AND ANTITRUST, at 15-49.

III. This Case Is the Right Vehicle to Resolve This Recurring Issue of Enormous Public Importance.

Respondents do not deny that this case is the Court's last chance to decide the exclusion payment issue without potentially having first to determine whether a complex business arrangement between the brand and generic constitutes a payment. *See* Pet. Br. 34-35; Hovenkamp, IP AND ANTITRUST, at 15-40 (noting "the increasing tendency of settling parties to complicate their settlements to dissuade antitrust scrutiny"). Respondents nevertheless assert that certiorari is inadvisable because this case arose before 2003, when Congress amended the statutory scheme to prevent the brand's settlement with the first-filing generic from raising a statutory bar to entry by later generics. *See* Bayer Br. 33. Respondents concede, however, that the Second Circuit held that the settlement

agreement in this case, despite arising before 2003, did not in fact raise such a statutory bar. *Id.* at 32.[5] So there is no distinction on this issue between this case and those arising after 2003.

Nor do Respondents deny that in 2003 Congress required exclusion payment agreements to be filed with the DOJ and FTC so that they would be prosecuted, or that Respondents' industry representatives had testified that this would solve the exclusion-payment problem because these agreements are unlawful under the Sherman Act. *See* Pet. Br. 4. Respondents now suggest that the Court should stay its hand and require that Congress specifically legislate against exclusion payments yet again. Bayer Br. 34; Barr Br. 22. But the proper interpretation of the Sherman Act is the responsibility of this Court, not Congress. *See State Oil Co. v. Khan*, 522 U.S. 3, 20 (1997) (courts have a clear mandate to shape rules that protect consumers); *see also Monell v. Dep't of Social Services*, 436 U.S. 658, 695 (1978) (Court should not "place on the shoulders of Congress the burden of the Court's own error"). Indeed, PhRMA and its allies are successfully forestalling further Congressional action by making this very point. *See, e.g., The Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706, Before H. Comm. on Energy and Commerce*, 111th Cong. (Mar. 31, 2009) (statement of PhRMA General Counsel, at 16) (arguing that courts, not Congress, should decide whether exclusion payments are anticompetitive).

---

5. The *legal bottleneck* issue is different from the *practical* delay that occurs -- both before and after 2003 -- as a result of a settlement with the first-filing generic (and that in fact occurred in this case). *See* Pet. Br. 26; Bayer Supp. App. 12a.

CONCLUSION

The petition should be granted.

Respectfully submitted,

STEVE D. SHADOWEN
Counsel of Record
MONICA L. REBUCK
HANGLEY ARONCHICK SEGAL
& PUDLIN
30 N. Third Street, Suite 700
Harrisburg, PA 17101
(717) 364-1030
sshadowen@hangley.com

Counsel for Petitioners
CVS Pharmacy, Inc.
and Rite Aid Corporation

TIMOTHY D. BATTIN
STRAUS & BOIES, LLP
4041 University Drive
Fairfax, VA 22030
(703) 764-8700

Counsel for Petitioner
Arthur's Drug Store, Inc.

BRUCE E. GERSTEIN
GARWIN GERSTEIN &
FISHER LLP
1501 Broadway, Suite 1416
New York, NY 10036
(212) 398-0055

DAVID F. SORENSEN
BERGER & MONTAGUE, P.C.
1622 Locust Street
Philadelphia, PA 19103
(215) 875-3000

Counsel for Petitioner
Louisiana Wholesale
Drug Co., Inc.

179

No. 10-762

Supreme Court, U.S.
FILED
JAN 7 - 2011
OFFICE OF THE CLERK

In the Supreme Court of the United States

LOUISIANA WHOLESALE DRUG CO., INC., CVS PHARMACY, INC., RITE AID CORPORATION, ARTHUR'S DRUG STORE, INC.,

Petitioners,

v.

BAYER AG, BAYER CORP., formerly doing business as Miles Inc., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., WATSON PHARMACEUTICALS, INC., BARR LABORATORIES, INC.,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF *AMICUS CURIAE* OF AARP IN SUPPORT OF PETITIONERS

STACY CANAN
Counsel of Record
BRUCE VIGNERY
AARP FOUNDATION LITIGATION

MICHAEL SCHUSTER
AARP

601 E STREET, NW
WASHINGTON, DC 20049
(202) 434-2060
scanan@aarp.org

Counsel for *Amicus Curiae* AARP

Becker Gallagher · Cincinnati, OH · Washington, D.C. · 800.890.5001

TABLE OF CONTENTS

Page

TABLE OF CONTENTS i

TABLE OF AUTHORITIES ii

INTEREST OF *AMICUS CURIAE* 1

SUMMARY OF ARGUMENT 2

REASONS FOR GRANTING THE WRIT 3

INTRODUCTION 3

I. THE SECOND CIRCUIT'S DECISION THAT EXCLUSION PAYMENTS ARE *PER SE* LAWFUL DEFEATS THE PROTECTIONS OF THE HATCH-WAXMAN ACT AND UNDERMINES ENFORCEMENT OF THE SHERMAN ACT 4

II. INCREASED USE OF EXCLUSION PAYMENTS PREVENTS COMPETITION AND HARMS CONSUMERS 7

CONCLUSION 12

TABLE OF AUTHORITIES

CASES

Cardinal Chem. Co. v. Morton Int'l, Inc.,
508 U.S. 83 (1993) 9

In re Barr Labs., Inc.,
930 F.2d 72 (D.C. Cir. 1991) 7

In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514 (E.D.N.Y. 2005) 4

STATUTES

Drug Price Competition and Patent Term Restoration Act,
21 U.S.C. § 355 5

35 U.S.C. § 282 3

LEGISLATIVE HISTORY

H. Rep. No. 98-857, pt. 1 (1984),
reprinted in 1984 U.S.C.C.A.N. 2647 6

Innovation and Patent Law Reform: Hearings on H.R. 3285, H.R. 3286, and H.R. 3605 Before the Subcomm. on Courts, Civil Liberties, and the Administration of Justice of the H. Comm. on the Judiciary, 38th Cong. 2d Sess., Part 1 (1984) 5

MISCELLANEOUS

AARP, *Rx Watchdog Report: Brand Name Drug Prices Continue to Climb Despite Low General Inflation Rate*, (May 2010), *available at* http://assets.aarp.org/rgcenter/ppi/health-care/i43-watchdog.pdf 5

AARP, *Rx Watchdog Report* (May 2010), *available at* http://www.aarp.org/health/Drugs-supplements/rx_watchdog.html 2

AARP, *Rx Watchdog Report*, Vol.6, Issue 4 (May 2009), *available at* http://assets.aarp.org/www.aarp.org_/cs/health/205256rxwatchdog may09.pdf 5, 6

Linda L. Barrett, Ph.D., *PrescriptionDrug Use Among Midlife and Older Americans,* AARP (2005), *available at* assets.aarp.org/rgcenter/health/rx_midlife_plus.pdf 1, 9

Comment of the Generic Pharmaceutical Ass'n in Support of Citizen Pet., FDA Docket No. 2004P-0075/CP1, at p. 3 (filed May 21, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00003-vol1.pdf 9

Families USA, *Cost Overdose: Growth in Drug Spending for the Elderly*, 1992-2010 (July 2000) 1

Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (Jan. 2010), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf..... 7, 10

Food and Drug Administration, *Protecting America's Health Through Human Drugs: Greater Access to Generic Drugs* (Jan. 2006), *available at* http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143545.htm 6

C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629 (2009)..... 10

Herbert Hovenkamp, et al., *Balancing Ease & Accuracy In Assessing Pharmaceutical Exclusion Payments*, 88 Minn. L. Rev. 712 (2004) 9

Kaiser Family Foundation, *Prescription Drug Trends*, (Sept. 2008), available at http://www.kff.org/rxdrugs/upload/3057_07.pdf..... 4

Jon Leibowitz, Chairman, Fed. Trade Comm'n, *How the Federal Trade Commission Works to Promote Competition and Benefit Consumers in a Dynamic Economy*, Before the Subcomm. on Antitrust, Competition Policy, and Consumer Rights (June 9, 2010) *available at* http://www.ftc.gov/os/testimony/100609dynamiceconomy.pdf 10

Bethany Mclean, *A Bitter Pill*, Fortune, Aug. 13, 2001 8

Prepared Statement of the Federal Trade Commission (Jan. 17, 2007), *available at* http://www.ftc.gov/speeches/leibowitz/070117Anticompetitivepatentsettlements_senate.pdf 8

Press Release, IMS Health, *IMS Health Reports U.S. Prescription Sales Grew 5.1 Percent in 2009, to $300.3 Billion*, Apr. 1, 2010, *available at* http://www.imshealthcom/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=d690a27e9d5b7210VgnVCM100000ed152ca2RCRD&vgnextchannel=41a67900b55a5110VgnVCM10000071812ca2RCRD&vgnextfmt=default. 4

Statement for the Record, American Medical Association, Subcom. on Commerce, Trade, and Consumer Protection for the House Committee on Energy and Commerce, *Impact of "Pay-for-Delay" Settlements On Patient Access to Affordable Generics and Overall Health Care System Costs*, (April 13, 2009) 10

The Wall Street Journal, *More Balk at Cost of Prescriptions*, Oct. 12, 2010..... 10

STATEMENT OF INTEREST OF *AMICUS CURIAE*[1]

AARP is a nonpartisan, nonprofit organization dedicated to addressing the needs and interests of people aged fifty and older. AARP has a long history of advocating for access to affordable health care and for controlling costs without compromising quality. Affordable prescription medication is particularly important to the older population which, because of its higher rates of chronic and serious health conditions, has the highest rate of prescription drug use. Persons over sixty-five, although only thirteen percent of the population, account for thirty-four percent of all prescriptions dispensed and forty-two cents of every dollar spent on prescription drugs. Families USA, *Cost Overdose: Growth in Drug Spending for the Elderly*, 1992-2010 at 2 (July 2000).

Significantly, in a 2005 AARP survey, one in four Americans, ages 50 and older, who took a prescription drug in the past five years said they did not fill a prescription written by their doctor in the past two years. Cost was reported as the main deterrent. Linda L. Barrett, Ph.D., *Prescription Drug Use Among Midlife and Older Americans,* AARP

---

[1] In accordance with Supreme Court Rule 37.6, *Amicus Curiae* states that: (1) no counsel to a party authored this brief, in whole or in part; and (2) no person or entity, other than *amicus*, their members and counsel have made a monetary contribution to the preparation or submission of this brief. Parties were timely informed with 10-days notice of the intent to file this *amicus* brief, and the written consents of the parties to the filing of this brief have been filed with the Clerk of the Court pursuant to Supreme Court Rule 37.3.

(2005), *available at* assets.aarp.org/rgcenter/health/rx_midlife_plus.pdf. Since prescription drug spending has skyrocketed over the last decade and a half, and national health expenditures on prescription drugs have quadrupled, AARP advocates for broader access to prescription drugs and lower prescription drug costs for consumers. *See, e.g.*, AARP, *Rx Watchdog Report* (May 2010), *available at* http://www.aarp.org/health/Drugs-supplements/rx_watchdog.html.

SUMMARY OF ARGUMENT

The ruling below that exclusion payment agreements are with few exceptions *per se* lawful under Section 1 of the Sherman Act will have a devastating impact on American consumers if left to stand. Prescription drug spending in the United States has skyrocketed over the last two decades. Competition from generic drugs is the most effective means of slowing the spiraling cost of pharmaceuticals. Generics typically sell for a fraction of the cost of their branded counterparts and quickly capture the majority of unit sales, thus having saved consumers over $734 billion in the past ten years. Recognizing the clear consumer benefit that accompanies generic drug competition, Congress sought to speed up generic entry by enacting the Hatch-Waxman Act.

Brand-name firms have used exclusion agreements to delay entry of generics an average of seventeen months and to terminate patent challenges that would otherwise generate *billions* of

dollars in consumer savings. Delaying the entry of affordable generic drugs not only prevents competition, but the lack of low cost treatment options reverberates throughout the entire health care system. Even for those patients who are insured but who are on fixed or limited incomes, having a generic option is often the difference between having access to a health care treatment and not having any treatment option at all. Economists at the FTC estimate that, if nothing changes, exclusion payment settlements will cost consumers $35 billion over the next ten years. If *Cipro* remains controlling law, the patent-challenge provisions of the Hatch-Waxman Act would be eviscerated, and American consumers would be left to pay the price.

REASONS FOR GRANTING THE WRIT

INTRODUCTION

The ruling below that exclusion payment agreements are with few exceptions *per se* lawful under Section 1 of the Sherman Act will have a devastating impact on American consumers if left to stand. According to the Second Circuit, the statutory rebuttable presumption of validity enjoyed by patents, 35 U.S.C. § 282, entitles patentees to pay alleged infringers not to contest validity and to stay out of the market.

Competition from generic drugs is one of the few effective means of slowing the spiraling cost of pharmaceuticals. Generics typically sell for a

fraction of the cost of their branded counterparts and quickly capture the majority of unit sales, saving consumers literally millions of dollars on a blockbuster drug such as Bayer Corporation's Cipro. If Barr Laboratories won its patent challenge, it intended to enter the market at a thirty percent discount to the price of brand name Cipro and expected to quickly capture a large percentage of the ciprofloxacin market. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 522 (E.D.N.Y. 2005) (Bayer estimated lost sales of up to $826 million during the first two years of generic competition).

I. THE SECOND CIRCUIT'S DECISION THAT EXCLUSION PAYMENTS ARE *PER SE* LAWFUL DEFEATS THE PROTECTIONS OF THE HATCH-WAXMAN ACT AND UNDERMINES ENFORCEMENT OF THE SHERMAN ACT.

Prescription drug spending in the United States has skyrocketed over the last two decades from $40 billion in 1990 to over $300 billion in 2009. Kaiser Family Foundation, *Prescription Drug Trends*, (Sept. 2008), *available at* http://www.kff.org/rxdrugs/upload/3057_07.pdf; Press Release, IMS Health, *IMS Health Reports U.S. Prescription Sales Grew 5.1 Percent in 2009, to $300.3 Billion*, Apr. 1, 2010, *available at* http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=d690a27e9d5b7210VgnVCM100000ed152ca2RCRD&vgnextchannel=41a67900b55

a5110VgnVCM10000071812ca2RCRD&vgnextfmt=default.

In the twelve month period ending with March 2010, the price of brand name prescriptions most widely used by Medicare beneficiaries increased by 9.7 percent, the highest rate of increase observed since AARP began tracking these prices in 2002. AARP, *Rx Watchdog Report: Brand Name Drug Prices Continue to Climb Despite Low General Inflation Rate*, (May 2010), *available at* http://assets.aarp.org/rgcenter/ppi/health-care/i43-watchdog.pdf. Competition from generic drugs is the most effective means of slowing the spiraling cost of pharmaceuticals. Generics typically sell for a fraction of the cost of their branded counterparts and quickly capture the majority of unit sales, thus having saved consumers over $734 billion in the past ten years. AARP, *Rx Watchdog Report*, Vol.6, Issue 4 (May 2009), *available at* http://assets.aarp.org/www.aarp.org_/cs/health/205256rxwatchdogmay09.pdf.

Recognizing the clear consumer benefit that accompanies generic drug competition, Congress sought to speed up generic entry by enacting the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355, commonly referred to as the Hatch-Waxman Act, which "institutionalize[d] and provide[d] incentive for a system of attacks on presumptively valid patents" by generic manufacturers. *Innovation and Patent Law Reform: Hearings on H.R. 3285, H.R. 3286, and H.R. 3605 Before the Subcomm. on Courts, Civil Liberties,*

and the Administration of Justice of the H. Comm. on the Judiciary, 38th Cong. 2d Sess., Part 1, at p. 444 (1984).

In creating the incentive to challenge patents, Congress was not seeking simply to line the pockets of the generic drug manufacturers. Hatch-Waxman challenges were supposed to be vehicles for earlier entry of generic drugs into the marketplace, thus giving consumers earlier access to lower-priced prescription drug alternatives. H. Rep. No. 98-857, pt. 1 at 1 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647 (explaining that the purpose of the Hatch-Waxman Act "is to make available more low cost generic drugs by establishing a generic drug approval procedure"). Indeed, generics make up nearly seventy percent of drugs prescribed today, whereas generics constituted only twelve percent of prescription drugs dispensed prior to the passage of the Hatch-Waxman Act. *See* AARP, *Rx Watchdog Report*, Vol.6, Issue 4 at 4. *See also*, Food and Drug Administration, *Protecting America's Health Through Human Drugs: Greater Access to Generic Drugs* (Jan. 2006), *available at* http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143545.htm.

The rise of exclusion payment agreements, however, has had a drastic effect on generic drug entry prior to patent expiration. Brand-name firms have used exclusion agreements to delay entry of generics an average of seventeen months and to terminate patent challenges that would otherwise generate *billions* of dollars in consumer savings.

Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 4 (Jan. 2010), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

Under the exclusion payment agreement here, for example, Bayer paid its generic competitors $398 million in exchange for the generics' agreement to stay out of the market for 6 1/2 of the remaining 7-year life of the Cipro patent. In other words, Defendants' agreement ensured that consumers would have to wait another 6 1/2 years to buy lower-priced generic ciprofloxacin. This delayed generic entry is the antithesis of what Congress intended when it enacted the Hatch-Waxman Act. *See In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991) ("Congress sought to get generic drugs into the hands of patients at reasonable prices-fast.").

II. INCREASED USE OF EXCLUSION PAYMENTS PREVENTS COMPETITION AND HARMS CONSUMERS.

At the end of 2008, brand name drug manufacturers were attempting to block generic entry on products with roughly $90 billion in pharmaceutical sales. FTC, *Pay-for-Delay*, *supra*, at 9. Delaying the entry of affordable generic drugs not only prevents competition, but the lack of low cost treatment options reverberates throughout the entire health care system. The price of a brand drug can be prohibitive for uninsured patients who do not have help covering the cost of their prescription drugs. Even for those patients who are insured but

who are on fixed or limited incomes, having a generic option is often the difference between having access to a health care treatment and not having any treatment option at all. When a generic pharmaceutical's entry into the market is delayed, it limits treatment access to vulnerable patient populations and prolongs the difficulty that physicians have in prescribing affordable treatment options.

The enormous consumer gains resulting from generic entry are well documented. The Federal Trade Commission (FTC) has found that successful patent challenges to just four major brand-name drugs (Prozac, Zantac, Taxol and Platinol) have saved consumers more than $9 billion. Prepared Statement of the Federal Trade Commission, at 4 (Jan. 17, 2007), *available at* http://www.ftc.gov/speeches/leibowitz/070117Anticompetitivepatentsettlements_senate.pdf. Had exclusion payments been permissible, none of these consumer savings likely would have occurred.

In the midst of Barr Laboratories' challenge to the patents protecting Eli Lilly's drug Prozac, for example, Barr stated that it would settle only if the settlement included an exclusion payment of at least $200 million. *See* Bethany Mclean, *A Bitter Pill*, Fortune, Aug. 13, 2001, at 5. Lilly refused the demand because, as acknowledged by Lilly's CEO, "such a settlement violated antitrust laws, and it isn't morally right." *Id.* So Barr continued litigating the case and ultimately obtained a judgment invalidating the Prozac patents. The resulting early

entry of generic Prozac saved consumers an estimated $2.5 billion. *See* Comment of the Generic Pharmaceutical Ass'n in Support of Citizen Pet., FDA Docket No. 2004P-0075/CP1, at p. 3 (filed May 21, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00003-vol1.pdf.

Allowing exclusion payments that "grant monopoly privileges to the holders of invalid patents," *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100-01 (1993), results in lost consumer health and welfare greatly disproportionate to the relatively modest costs of patent litigation. *See* Herbert Hovenkamp, *et al.*, *Balancing Ease & Accuracy In Assessing Pharmaceutical Exclusion Payments*, 88 Minn. L. Rev. 712, 717 (2004).

In addition to consumers skipping doses of prescribed medicines due to the high cost of the medicines or co-payments, Barrett, *supra*, a practice known as abandonment, which occurs when a patient refuses to purchase a prescription that was filled by a pharmacist, has been on the rise in 2010. Patients with private health insurance abandoned nearly one in ten new prescriptions for brand-name drugs in the second quarter of 2010. This increase comes as patients see a rise in the cost of prescription medications, like a mother in Montana who arrived at a pharmacy to discover that medication for her depression and her son's asthma would cost her $335 despite her private insurance. The mother abandoned both prescriptions before purchasing a cheaper, alternative medication for her

son. The Wall Street Journal, *More Balk at Cost of Prescriptions*, Oct. 12, 2010 (citing data from a Wolters Kluwer Pharma Solutions study).

When patients do not obtain necessary treatment because no financially feasible options are available, conditions left untreated will worsen and result in a higher cost of care over time. Statement for the Record, American Medical Association, Subcom. on Commerce, Trade, and Consumer Protection for the House Committee on Energy and Commerce, *Impact of "Pay-for-Delay" Settlements On Patient Access to Affordable Generics and Overall Health Care System Costs* (April 13, 2009).

Economists at the FTC estimate that, if nothing changes, exclusion payment settlements will cost consumers $35 billion over the next ten years. FTC, *Pay for Delay, supra*, at 2; *see also* C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 650 (2009) (estimating that exclusion payments have already cost consumers over $12 billion).

For this reason, one of the FTC's top priorities is stopping "pay-for-delay" agreements between brand-name pharmaceutical companies and generic competitors that delay the entry of lower-priced generic drugs into the market. FTC Chairman Leibowitz recently noted that, "[a]greements to eliminate potential competition and share the resulting profits are at the core of what the antitrust laws proscribe, and for that reason the Commission

believes strongly that these pay-for-delay settlements are prohibited under the antitrust laws." Jon Leibowitz, Chairman, Fed. Trade Comm'n, *How the Federal Trade Commission Works to Promote Competition and Benefit Consumers in a Dynamic Economy*, Before the Subcomm. on Antitrust, Competition Policy, and Consumer Rights (June 9, 2010) *available at* http://www.ftc.gov/os/testimony/100609dynamiceconomy.pdf.

If *Cipro* remains controlling law, allowing settlements between brand-name and generic firms through exclusion payment agreements, the patent-challenge provisions of the Hatch-Waxman Act would be eviscerated, and American consumers would be left to pay the price.

CONCLUSION

For the foregoing reasons, AARP urges the Court to grant the petition for a *writ of certiorari*.

January 7, 2011 Respectfully submitted,

Stacy Canan
Counsel of Record
Bruce Vignery
AARP Foundation Litigation

Michael Schuster
AARP

601 E Street, NW
Washington, DC 20049
Tel. (202) 434-2060
Fax (202) 434-6424
scanan@aarp.org
bvignery@aarp.org
mschuster@aarp.org

Counsel for *Amicus Curiae*
AARP

179

(4)

No. 10-762

Supreme Court, U.S.
FILED
JAN 7 - 2011
OFFICE OF THE CLERK

In The
Supreme Court of the United States

LOUISIANA WHOLESALE DRUG CO., INC., CVS PHARMACY, INC., RITE AID CORPORATION, ARTHUR'S DRUG STORE, INC.,

Petitioners,

v.

BAYER AG, BAYER CORP., formerly doing business as Miles Inc., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., WATSON PHARMACEUTICALS, INC., BARR LABORATORIES, INC.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit

BRIEF OF *AMICUS CURIAE* THE AMERICAN ANTITRUST INSTITUTE IN SUPPORT OF PETITIONERS

PAUL E. SLATER
SPERLING & SLATER, P.C.
55 West Monroe Street, Suite 3200
Chicago, IL 60603
(312) 641-3200
pes@sperling-law.com
Counsel for Amicus Curiae American Antitrust Institute

COCKLE LAW BRIEF PRINTING CO (800) 225-6964
OR CALL COLLECT (402) 342-2831

TABLE OF CONTENTS

	Page
INTEREST OF *AMICUS CURIAE*	1
BACKGROUND	2
STATEMENT OF THE CASE	7
SUMMARY OF ARGUMENT	12
REASONS FOR GRANTING THE PETITION	14
I. The Court Should Grant Review Because the Decision Below Was Wrongly Decided and Directly Conflicts with the Decisions of This Court	14
II. The Court Should Grant Review in Order to Resolve the Split Among the Circuits	19
CONCLUSION	21

TABLE OF AUTHORITIES

Page

CASES

Andrx Pharmaceutical Inc. v. Biovail Corp. Intl., 256 F.3d 799 (D.C. Cir. 2001), *cert. denied*, 535 U.S. 931 (2002) 5, 13, 20

Arkansas Carpenters Health and Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. 2010) .....*passim*

In re Berwyn E. Etter, 756 F.2d 852 (Fed. Cir. 1985) 17

Blonder-Tongue Labs, Inc. v. Univ. of Ill. Found., 402 U.S. 313 (1971) 17

In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharm., Inc. v. Kroger Co.*, 543 U.S. 939 (2004) 10, 13, 19

In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 2828 (2009) .....*passim*

Joblove v. Barr Labs., Inc. (In re Tamoxifen Citrate Antitrust Litigation), 466 F.3d 187 (2d Cir. 2005) .....*passim*

Microlux Biosystems, Inc. v. Biowhittaker, Inc., 172 F.Supp.2d 680 (D. Md. 2000) 16

Palmer v. BRG of Georgia, Inc., 498 U.S. 46 (1990) 15, 16

Schering-Plough Corp. v. Federal Trade Commission, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006) 6, 13, 20

Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530 (Fed. Cir. 1983) 17

TABLE OF AUTHORITIES – Continued

Page

In re Terazosin Hydrochloride Antitrust Litigation, 352 F.Supp.2d 1279 (S.D. Fl. 2005) 11, 20

U.S. v. Glaxo Group, Ltd., 410 U.S. 52 (1973) 17

U.S. v. Microsoft Corp., 253 F.3d 34 (D.C. Cir. 2001) 4, 16

U.S. v. Singer Mfg. Co., 374 U.S. 174 (1963) 15

U.S. v. Topco Assoc., 405 U.S. 596 (1972) 15, 16

Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294 (11th Cir. 2003), *cert. denied*, 543 U.S. 934 (2004) 6

STATUTES

15 U.S.C. §1 13

21 U.S.C. §355 ..... 2, 3, 17

35 U.S.C. §271 3

35 U.S.C. §282 5

OTHER AUTHORITIES

Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002) 4

XII Herbert Hovenkamp, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 2030b (2d ed. 2005) 4

In re Schering-Plough Corp., FTC Docket No. 9297, 2003 WL 22989651 (2003) 5, 10, 18

INTEREST OF *AMICUS CURIAE*[1]

The American Antitrust Institute ("AAI") is an independent non-profit education, research, and advocacy organization. Its mission is to advance the role of competition in the economy, protect consumers, and sustain the vitality of the antitrust laws. The Advisory Board of AAI, which serves in a consultative capacity,[2] consists of prominent antitrust lawyers, law professors, economists, and business experts. *See* http://www.antitrustinstitute.org.

AAI's Board of Directors has authorized the filing of this brief because it believes that the Second Circuit's economic and legal reasoning is flawed and seriously threatens competition. If left standing, the opinion will undermine the careful statutory scheme that seeks to prevent weak or narrow patents from blocking the market entry of generic drugs and reducing competition. The stakes for consumers are high. The opinion of the Second Circuit Court of Appeals will encourage and allow brand name pharmaceutical

---

[1] All parties were advised of the AAI's intention to file an *amicus* brief more than ten days prior to its due date. The written consents of all parties to the filing of this brief have been lodged with the Clerk. No counsel for a party has authored this brief in whole or in part, and no person or entity other than AAI or its counsel has made a monetary contribution to the preparation or submission of this brief.

[2] The AAI is managed by its Board of Directors. The individual views of members of the Advisory Board may differ from the positions taken by AAI.

manufacturers to pay generic competitors to keep their cheaper generic drugs off the market.

BACKGROUND

Competition from generic drug manufacturers is one of the few constraints on the rising cost of brand-name drugs. Generic drugs typically sell for a fraction of the price of their branded counterparts. That price differential allows generic entrants to quickly capture a majority of the unit sales from the higher priced branded drugs, thereby saving consumers billions of dollars on blockbuster drugs such as Ciprofloxacin ("Cipro").

In order to encourage market entry by generic drugs and the attendant price competition, Congress promulgated the Drug Price Competition and Patent Restoration Act of 1984 (the "Hatch-Waxman Act"). The Hatch-Waxman Act encourages generic firms to challenge the validity of pharmaceutical patents by allowing them to statutorily infringe the patent without subjecting themselves to infringement damages. Specifically, when a generic firm applies to the FDA for the right to sell a generic drug, it can certify, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), either that the pertinent brand patent is invalid or that the generic version of that drug does not infringe the patent. This so-called "Paragraph IV Certification" by a generic firm is made an act of infringement by the Hatch-Waxman Act and gives the patentee

an immediate cause of action against the potential market entrant. 35 U.S.C. §271(e)(1)-(2). Because the generic firm has neither made nor sold the generic product, its act of infringement causes no damage to the patentee. As stated in the opinion below, "the Hatch-Waxman Act . . . allow[s] generic manufacturers to challenge the validity of the patent without incurring . . . the risks of damages from infringement." *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, 604 F.3d 98, 101 (2d Cir. 2010).

The Hatch-Waxman Act further encourages generic firms to challenge pharmaceutical patents by giving the first generic firm to make a Paragraph IV Certification a 180-day period of exclusivity. 21 U.S.C. §355(j)(5)(B)(iv). During this period of exclusivity, the generic firm will be the only low-priced alternative to the patented drug and it may be able to obtain a foothold on generic sales that will last beyond the 180-day period. The 180-day period of exclusivity begins to run when the generic firm begins marketing its version of the drug or when a final judicial order issues determining that the patent is either invalid or not infringed, whichever occurs first. *Id.*

This congressional scheme, when not circumvented by the type of conduct at issue in this case, has succeeded in encouraging generic firms to challenge and set aside through litigation weak pharmaceutical patents. According to the Federal Trade Commission ("FTC"), when generic firms have been sued for infringement after making a Paragraph IV Certification, they have prevailed at the patent trial

in 73% of the tried cases. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

In order to avoid such judicial scrutiny of their patents many pharmaceutical patentees have entered into "reverse" or "exclusion" payment settlement agreements. Under these agreements, the generic firm typically (1) drops its challenge to the validity of the patent or its denial of the patentee's claim of infringement, and (2) agrees to respect the patent and not attempt to enter the market until it is about to expire. In return, the patentee pays the generic challenger tens of millions or hundreds of millions of dollars. These payments are made by the patentee to the generic firm even though the generic firm has not alleged that the patentee owes it any money. Such reverse payments are fairly characterized as the purchase by the patentee of the generic firm's agreement to cease its efforts to enter the market and compete against the patented drug.

It is unlawful under the Sherman Act to pay an actual or potential competitor to stay out of the market. This rule applies regardless of the degree of certainty that the potential competitor, absent the payment, would, in fact, be able to successfully enter the market. *See, e.g.,* XII Herbert Hovenkamp, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 2030b at 213 (2d ed. 2005); *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (*en banc*). The Court of Appeals for the

Sixth Circuit therefore held in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 914 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharm., Inc. v. Kroger Co.*, 543 U.S. 939 (2004), that a reverse exclusion payment agreement between a generic manufacturer and a patentee is "a plain vanilla horizontal agreement to restrain trade" which is unlawful *per se*. Despite the rebuttable presumption of patent validity under 35 U.S.C. §282, the Sixth Circuit held that some patents are "'paper tiger[s]' incapable of deterring a generic producer from entering the market. . . ." 332 F.3d at 915. The Court further noted that if the patentee "had . . . been confident of the independent durability of its patent and the validity of its infringement claim, it would not have paid $89 million to effect what the patent and infringement suit had already accomplished." *Id.* The D.C. Circuit, considering the same agreement that was at issue in *Cardizem*, likewise held that it was anticompetitive. *Andrx Pharm., Inc. v. Biovail Corp. Intl.*, 256 F.3d 799, 813 (D.C. Cir. 2001) (stating that a reverse exclusion payment was "presumably in return for something that Andrx would not otherwise do, that is, delay marketing of its generic").

The FTC has similarly held that if the patent alone was sufficient to deter market entry then a reverse payment to a generic firm would not be necessary. As a result, the FTC held that reverse payment agreements should be deemed presumptively anticompetitive and unlawful. *In re Schering-Plough Corp.*, FTC Docket No. 9297, 2003 WL 22989651

(Dec. 8, 2003). That decision, however, was vacated by the Court of Appeals for the Eleventh Circuit. *Schering-Plough Corp. v. Federal Trade Commission*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006). The Court relied heavily on the opposite presumption – *i.e.*, that the patent should be presumed valid. *Id.* at 1066. Indeed, the Court went so far as to presume that the accused product infringed the patent in question. *Id.* ("By virtue of its '743 patent, Schering obtained the legal right to exclude Upsher and ESI from the market until they prove . . . that their products . . . did not infringe Schering's patent"). *See also Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1304 (11th Cir. 2003), *cert. denied*, 543 U.S. 934 (2004).

The opinion below goes a step beyond the Eleventh Circuit analysis. The Second Circuit holds that exclusion payments are *per se lawful* unless the plaintiff proves that the patent was procured by fraud or that the infringement action is brought in such bad faith as to constitute a sham. 604 F.3d at 106. Under this approach, mere invalidity or non-infringement of the patent is insufficient to allow the reverse payment agreement to be challenged under the antitrust laws. Unless accompanied by egregious conduct such as fraud or bad faith, the Second Circuit places reverse payment agreements beyond the reach of the Sherman Act, as a matter of law.

As explained below, the AAI believes it is time for this Court to resolve the question of what standard should be used to determine whether a reverse

exclusion payment agreement is beyond the reach of the antitrust laws.

STATEMENT OF THE CASE

In the case below, Bayer owned the patent to ciprofloxacin hydrochloride ("Cipro"), one of the most prescribed antibiotics in the world. The generic manufacturer, Barr, was a potential entrant into the Cipro market. In 1991, twelve years before the Cipro patent was to expire, Barr filed a Paragraph IV Certification indicating that it would enter the Cipro market with a generic version of that drug. 604 F.3d 98, 100-01. In response, Bayer sued Barr for infringement. *Id.* at 101-02.

Two weeks before the patent trial was to commence, Bayer and Barr agreed to a reverse payment settlement. *Id.* at 102. Bayer, which faced no claim for money damages, agreed to pay Barr, the accused infringer, $398 million. In return, Barr agreed not to enter the Cipro market until only six months remained on the patent and stipulated that the patent was valid. *Id.*; Pet. App. at 42(a).

Direct purchasers of Cipro filed an antitrust suit alleging that the reverse payment agreement was a horizontal combination between competitors that allocated the Cipro market to Bayer. *Id.* at 102-03. The antitrust trial court granted summary judgment for the defendants. It held that whether the reverse payment agreement had adversely affected

competition for ciprofloxacin was not "the crux of the matter." *Id.* Rather the *only* pertinent question was whether the adverse effects on competition stemming from the reverse payment agreement were within the scope of the Cipro patent. *Id.* The trial court reasoned that any other "approach would undermine the presumption of validity of patents in all cases." *Id.*

The Second Circuit affirmed. It did so reluctantly, noting that after the trial court entered judgment for the defendants in *Cipro*, a panel of the Second Circuit had decided *Joblove v. Barr Labs., Inc. (In re Tamoxifen)*, 466 F.3d 187 (2d Cir. 2005), and "held that reverse payment settlements of patent lawsuits do not violate antitrust laws." Pet. App. 10a. The Second Circuit stated that "[b]ecause *Tamoxifen* is dispositive of plaintiffs' claims, we AFFIRM." *Id.* But, the Second Circuit also stated "because of the 'exceptional importance' of the antitrust implications of reverse exclusionary payment settlements of patent infringement suits, we invite plaintiffs-appellants to petition for rehearing in banc" so that the *Tamoxifen* holding could be reconsidered. Pet. App. 10a.

In *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2005) ("*Tamoxifen*"), a pharmaceutical patentee agreed to pay a generic manufacturer $21 million and the generic manufacturer agreed not to challenge the validity of the *Tamoxifen* patent or enter the market with a generic version of the patented drug until the patent expired. This reverse payment settlement agreement was entered

into after the patent was held invalid at trial, but before the appeal. *Id.* at 193-94.

Direct purchasers of the patented drug subsequently sued the patentee and the generic manufacturer alleging that the reverse payment agreement violated the Sherman Act. The trial court granted the defendant's motion to dismiss. The Second Circuit affirmed, holding that the antitrust plaintiffs had failed, as a matter of law, to state a claim. Specifically, this Court stated:

> So long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is *presumably entitled*: a lawful monopoly over the manufacture and distribution of the patented product.

and

> Unless and until the patent is shown to have been procured by a fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law as long as competition is restrained only within the scope of the patent.

Id. at 208-09, 213 (emphasis added).

In so holding, the *Tamoxifen* Court acknowledged that the reverse payment agreement would allow the patentee to continue earning monopoly profits, which it could then share with the retreating generic entrant,

and further acknowledged that as a result of the reverse payment agreement consumer prices would likely be higher than if market entry had occurred. *Id.* at 208-09. Nonetheless, the Second Circuit held that reverse payment agreements were necessarily beyond the reach of the antitrust laws because the patentee was "presumably entitled" to its "monopoly over the manufacture and distribution of the patented product." *Id.* at 213. In effect the Court presumed that the patent was valid and infringed and that the patentee's monopoly was, therefore, lawful.

In following *Tamoxifen*, the *Cipro* Court was not unaware that the *Tamoxifen* decision was controversial and contrary to the views of the FTC, United States Department of Justice and other Circuits. 604 F.3d at 104-05.[3] The Second Circuit acknowledged that the FTC "has long insisted that reverse exclusionary payment settlements violate antitrust law"; that the United States believes reverse payment patent settlements should be deemed presumptively illegal; and that "many academic commentators share [that] view." 604 F.3d at 104-05. The Second Circuit further acknowledged that in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 908 (6th Cir. 2003),

---

[3] United States: *See* Brief *Amicus Curiae* of the United States in Support of Rehearing in Banc, submitted to the Second Circuit Court of Appeals in the case below, at 9-10, 28-29; *also* 604 F.3d at 109. FTC: *In re Schering-Plough Corp.*, FTC Docket No. 9297, 2003 WL 22989651 (FTC 2003), *rev'd.*, 402 F.3d 1056 (11th Cir. 2005).

the Sixth Circuit held reverse exclusionary payment agreements "to be *per se* illegal." 604 F.3d at 105. *See also In re Terazosin Hydrochloride Antitrust Litigation*, 352 F.Supp.2d 1279 (S.D. Fl. 2005) (holding reverse exclusionary payment agreements *per se* unlawful).

Nonetheless, the *Cipro* Court adhered to the *Tamoxifen* holding that "the plaintiffs had no antitrust claim because a patent holder is entitled to protect its 'lawful monopoly over the manufacture and distribution of the patented product.'" 604 F.3d at 105-06. The *Cipro* Court then explicitly adopted the *Tamoxifen* test that unless the patent was procured by fraud or the claim of infringement was an objectively baseless sham, an injury to competition could not be found. 604 F.3d at 106. The *Cipro* Court concluded that it was bound by precedent to follow *Tamoxifen*, which had "rejected antitrust challenges to reverse payments as a matter of law." *Id.*

The Petitioners herein accepted the Second Circuit's invitation to file for rehearing in banc. Their petition was denied. Pet. App. 2a. Circuit Judge Rosemary S. Pooler dissented. Judge Pooler noted that reverse payment settlement agreements had become increasingly common and that the *Tamoxifen* decision "has played a significant role in encouraging this unfortunate practice." Pet. App. 3a-4a. Judge Pooler further noted that the FTC had found that, subsequent to *Tamoxifen*, 53 reverse payment pharmaceutical patent settlements had been executed and that those settlements cost consumers approximately $3.5 billion

per year. Pet. App. 4a-5a. Judge Pooler agreed with the position of the United States that the *Tamoxifen* rule was "incorrect" (Pet. App. 7a) and stated that reverse payment settlement agreements "serve no obvious redeeming social purpose." Pet. App. 5a. Dissenting from the denial of rehearing in banc, Judge Pooler stated "[i]t will now be up to the Supreme Court or Congress to resolve the conflict among the Courts of Appeals." Pet. App. 8a.

SUMMARY OF ARGUMENT

The decision below should be reviewed by this Court for two reasons. First, the rule announced in *Tamoxifen* and followed in *Cipro* is incorrect and seriously compromises the public interest in having competition drive pharmaceutical prices lower. The holding below is incorrect because the Second Circuit wrongly presumes that the Cipro patent is valid and infringed unless the patentee is guilty of fraud or bad faith. In so doing, the Second Circuit presumes its conclusion in all but those cases where the patentee is guilty of intentional misconduct. In actuality, the presumption of patent validity is merely a procedural rule that assigns burdens of proof. It is not a presumption of substantive validity and it is not irrebuttable except in cases of bad faith or fraud. Furthermore, the law has never recognized a presumption of infringement. By presuming that the patent is valid and infringed, the Second Circuit circumvents the controlling decisions of this Court.

Those decisions hold that a horizontal agreement between a market participant and a potential entrant, that eliminates the possibility of entry, unlawfully restrains competition. This Court has also held that a patent settlement agreement that incorporates anticompetitive terms is violative of the Sherman Act. The need to apply these holdings to the facts of the *Cipro* litigation should not have been obviated by unsupported presumptions.

Second, the decision below sharply conflicts with the decision of the Sixth Circuit in *In re Cardizem Antitrust Litigation*, 332 F.3d 896, 907 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharm., Inc. v. Kroger Co.*, 543 U.S. 939 (2004). In that case, the Court held that reverse payment patent settlements are *per se* violations of §1 of the Sherman Act (15 U.S.C. §1). This also appears to be the rule in D.C. Circuit. *Andrx Pharmaceutical Inc. v. Biovail Corp. Intl.*, 256 F.3d 799 (D.C. Cir. 2001), *cert. denied*, 535 U.S. 931 (2002).

The Eleventh Circuit has rejected the *per se* approach but also disagrees with the *Cipro/Tamoxifen* line of decisions. It holds that reverse payment agreements are unlawful if the generic firm proves that the patent is either invalid or not infringed. *Schering-Plough Corp. v. Federal Trade Commission*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006).

The United States and the FTC take still another course. They both assert that reverse payment patent settlements are presumptively unlawful

These various rules and approaches have led to inconsistent application of the law and uncertainty with regard to a matter of significant public concern. The AAI respectfully submits that this Court should review the decision below so that the correct rule will be uniformly applied to reverse payment patent settlements.

REASONS FOR GRANTING THE PETITION

I. The Court Should Grant Review Because the Decision Below Was Wrongly Decided and Directly Conflicts with the Decisions of This Court

AAI respectfully submits that the case below and its foundation, *Tamoxifen*, were wrongly decided. Both decisions are based on two interrelated and incorrect propositions. First, both cases confuse the right of a patentee to exclude others from making the patented device with a supposed right to pay potential competitors not to test the validity of a patent which may or may not be valid or infringed. Second, both decisions misapprehend the legal presumption of patent validity. That presumption is a procedural tool that merely determines who has the burden of proof when a patent is challenged. It is not a substantive rule of patent validity and is not irrebuttable in the absence of fraud or bad faith – as *Tamoxifen* clearly holds.

This Court has held that the antitrust laws protect both actual and potential competition. Thus,

the Sherman Act prohibits not only agreements that restrain competition, but also those that restrain market entry. *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49-50 (1990) (agreement between competitor and potential entrant that the potential entrant would not attempt to enter the competitor's market held to unlawfully restrain competition); *U.S. v. Topco Assoc.*, 405 U.S. 596 (1972) (agreement between competitors not to attempt to enter each other's market held unlawful). Furthermore, the fact that otherwise anti-competitive terms are embodied in a patent settlement agreement provides no defense. If the terms of a patent settlement agreement unreasonably restrains competition, they violate the Sherman Act. *U.S. v. Singer Mfg. Co.*, 374 U.S. 174 (1963) (patent settlement agreement excluding foreign competitors from the U.S. market held *per se* unlawful).

When a market is dominated by a competitor with a blocking patent, a potential market entrant must successfully defeat the patentee's contention that the patent is valid and that the competitor's device infringes it in order to successfully enter the market. The necessity of accomplishing this task is analytically no different than the need for a new entrant to build a plant or procure access to scarce materials. In either event, the new entrant must invest time, effort and capital in the pursuit of a goal that it might or might not successfully achieve. No one would suggest, however, that an agreement to pay a potential market entrant millions of dollars not to build a plant or attempt to enter the market would be lawful. To the contrary, this Court has repeatedly

held that an agreement precluding a potential competitor from entering the market is "unlawful on its face." *Palmer*, 498 U.S. at 50; *Topco*, 405 U.S. at 608 (agreement precluding potential competitors from entering a co-competitor's market held *per se* unlawful).[4] As stated by the United States in its *amicus* brief to the Second Circuit in support of rehearing in banc in the case below, the Sherman Act does not permit patent holders "to contract their way out of the statutorily imposed risk that the patent litigation could lead to invalidation of the patent while claiming antitrust immunity for that private contract." 604 F.3d at 108-09. The United States further argued that *Tamoxifen* "inappropriately" allows patentees to do just that while offering "no protection to the public interest in eliminating undeserved patents." *Id.*

Tamoxifen's holding that reverse payment agreements do not injure competition because the patentee is "presumably entitled" to its patent monopoly (466 F.3d 208-09, 213) is also incorrect. The patent law

---

[4] *See also* XII Herbert Hovenkamp, ANTITRUST LAW, ¶ 2030(b) at 213 (2d ed. 2005) ("the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition"); *Microsoft*, 253 F.3d at 78-79 (rejecting the contention that no injury to competition could be shown unless the new entrant, in fact, would have successfully developed its new product); *Microlux Biosystems, Inc. v. Biowhittaker, Inc.*, 172 F.Supp.2d 680, 685-86 (D. Md. 2000) (agreement preventing plaintiff from obtaining needed materials held to be "obvious[ly]" anticompetitive even though the plaintiff would have needed to overcome numerous obstacles to successfully enter the market).

provides no such iron-clad presumption in favor of validity. Indeed, Congress specifically provided for judicial review of patent validity and the presumption of validity is only "a procedural device, not substantive law." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983). It merely assigns burdens to patent litigants and does not "acquire an independent evidentiary role in any [other] proceeding." *In re Berwyn E. Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985). Indeed, far from presuming substantive validity, the Hatch-Waxman Act and the opinions of this Court explicitly encourage generic manufacturers to challenge patents and protect the public interest by testing them in Court. *See* 21 U.S.C. §355(j)(5)(B)(iv) and (vii)(IV); *Blonder-Tongue Labs, Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 344 (1971) (patent law "encourage[s] authoritative testing of patent validity"); *U.S. v. Glaxo Group, Ltd.*, 410 U.S. 52, 58 (1973) ("it is . . . important to the public that competition should not be repressed by worthless patents").

AAI does not here address the question of what substantive rule should be employed to determine whether a reverse payment agreement unreasonably injures competition. AAI submits that the question should be addressed on the merits by this Court. For current purposes, AAI submits only that the holding in *Tamoxifen*, adopted and followed in the decision below, is plainly incorrect and raises questions of exceptional importance to the public and to the proper enforcement of the antitrust laws in a patent setting.

If a pharmaceutical patent is valid and infringed, then the patentee has the right under the patent statutes to exclude the generic drug from the market without unlawfully restraining competition. The question, however, which is raised by *Cipro* and *Tamoxifen*, is whether a patentee can pay a potential generic entrant not to test the validity of the patent or whether the patent is infringed by the generic version of the drug without running afoul of the antitrust laws. Clearly, if the patent is either invalid or not infringed, then the reverse payment agreement acts as a restraint on potential horizontal competition that the patent statutes do not permit. The question, of course, is what analytical rule structure will be used to determine whether competition was unreasonably restrained when it is the infringement suit itself that has been settled. In its *amicus* brief to the Second Circuit, the United States proposed that a rule of reason be employed and that "reverse payments substantially in excess of anticipated litigation costs" should be deemed "presumptively unlawful" unless the defendant can provide "a reasonable explanation of the payment." U.S. *Amicus* Brief, 9-10, 28-29; 604 F.3d at 109. The FTC has similarly taken the position that reverse payment settlement agreements should be deemed presumptively unlawful. *In re Schering-Plough Corp.*, FTC Docket No. 9297, 2003 WL 22989651 (2003), *rev'd*, 402 F.3d 1056 (11th Cir. 2005). Other approaches are possible. AAI respectfully submits, however, that the *Cipro/Tamoxifen* approach, which allows the antitrust laws to function only where the patentee is guilty of fraud or has acted in

bad faith, gives far too much latitude to the patentee and the generic entrant to pursue their own financial gain and far too little protection to the public's interest in competitive markets.

II. The Court Should Grant Review in Order to Resolve the Split Among the Circuits

It is undisputed that the circuits are split on whether reverse payment agreements "fall within the scope of the patent holder's property right or whether such settlements are properly characterized as illegal market sharing agreements." 604 F.3d at 104-05. Indeed, the Court below acknowledged that the "[a]uthorities are divided on this question." *Id.* at 105.

In the Second Circuit the *Tamoxifen/Cipro* rule prevails and reverse payment agreements are presumed, as a matter of law, not to violate the Sherman Act unless the patentee is guilty of fraud or bad faith. The questions of whether the patent is merely weak, invalid or not infringed are irrelevant to the analysis. The Federal Circuit agrees with the Second Circuit's formulation. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 2828 (2009).

The Sixth Circuit has taken the diametrically opposed position. In *In re Cardizem CD Antitrust Litigation*, the Court characterized the reverse payment settlement of $89.83 million as a payment by the patentee to the generic firm to keep "its generic product off the market" (332 F.3d at 907) and stated:

> There is simply no escaping the conclusion that the Agreement . . . was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade.

332 F.3d at 908. This also appears to be the approach taken by the D.C. Circuit. *Andrx Pharm., Inc. v. Biovail Corp. Intl.*, 256 F.3d 799 (D.C. Cir. 2001), *cert. denied*, 535 U.S. 931 (2002). *See also In re Terazosin Hydrochloride Antitrust Litigation*, 352 F.Supp.2d 1279 (S.D. Fl. 2005) (reverse payment settlement agreement held *per se* unlawful).

The Eleventh Circuit has charted a third course. In *Schering-Plough Corp. v. Federal Trade Commission*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006), it explicitly rejected the use of the *per se* rule or the rule of reason. 402 F.3d at 1064, 1065 ("neither the rule of reason nor the *per se* analysis is appropriate"). Rather than analyzing the competitive effect of the agreement, *Schering* requires a determination of whether the patent is in fact valid and infringed and places the burden of proof on the antitrust plaintiff. Thus, *Schering* holds that market exclusion, even if it injures competition, does not go beyond what is permitted by the patent "unless and until" the patent is proved invalid or not infringed. 402 F.3d at 1066-67. This, of course, requires the relitigation of the patent issues in the antitrust case, but at least it does not simply presume validity and infringement as does the *Cipro/Tamoxifen* approach.

AAI respectfully submits that the divergence among the Circuits is dramatic and troublesome. The importance of generic entry into pharmaceutical markets and the cost to consumers if cases are wrongly decided strongly supports granting the Petition. There should be one national approach for how reverse payment pharmaceutical settlement agreements are treated; and that approach should be consistent with the intent of the Hatch-Waxman Act, the Sherman Act, and the patent statutes, all of which encourage or permit challenges to patents that may be invalid or not infringed.

CONCLUSION

For the reasons stated above, the American Antitrust Institute respectfully submits that the Court should grant the petition for certiorari.

Dated: January 6, 2011

Respectfully submitted,

PAUL E. SLATER
SPERLING & SLATER, P.C.
55 West Monroe Street
Suite 3200
Chicago, IL 60603
(312) 641-3200
pes@sperling-law.com
Counsel for Amicus Curiae
American Antitrust Institute

179

(3)

No. 10-762

Supreme Court, U.S.
FILED
JAN 7 - 2011
OFFICE OF THE CLERK

In The
Supreme Court of the United States

LOUISIANA WHOLESALE DRUG CO., INC., CVS PHARMACY, INC., RITE AID CORPORATION, ARTHUR'S DRUGSTORE, INC.,

Petitioners,

v.

BAYER AG, BAYER CORP., formerly doing business as MILES INC., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., WATSON PHARMACEUTICALS, INC., BARR LABORATORIES, INC.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit

BRIEF OF THE STATES OF CALIFORNIA, ARIZONA, ARKANSAS, DELAWARE, FLORIDA, HAWAII, IDAHO, ILLINOIS, IOWA, MAINE, MARYLAND, MASSACHUSETTS, MINNESOTA, MISSISSIPPI, MISSOURI, MONTANA, NEBRASKA, NEVADA, NEW HAMPSHIRE, NEW MEXICO, NORTH CAROLINA, OKLAHOMA, OHIO, OREGON, SOUTH CAROLINA, TENNESSEE, TEXAS, UTAH, VERMONT, WASHINGTON, WEST VIRGINIA AND WYOMING AS AMICI CURIAE SUPPORTING PETITIONERS

KAMALA D. HARRIS
Attorney General of California
MANUEL M. MEDEIROS
State Solicitor General
J. MATTHEW RODRIQUEZ
Chief Assistant Attorney General
KATHLEEN E. FOOTE
Senior Assistant Attorney General
CHERYL L. JOHNSON
Deputy Attorney General
Counsel of Record
300 South Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 897-2688
Fax: (213) 897-2801
Cheryl.Johnson@doj.ca.gov
Counsel for Amici Curiae

[Additional Counsel Listed On Inside Cover]

COCKLE LAW BRIEF PRINTING CO (800) 225-6964
OR CALL COLLECT (402) 342-2831

Additional Counsel For Amici Curiae

DUSTIN MCDANIEL
Attorney General
State of Arkansas
323 Center Street
Little Rock, AR 72201
(501) 682-2007

TOM HORNE
Attorney General
State of Arizona
1275 W. Washington Ave.
Phoenix, AZ 85007
(602) 542-5025

JOSEPH R. "BEAU" BIDEN, III
Attorney General
State of Delaware
820 N. French Street
Wilmington, DE 19801
(302) 577-8500

PAMELA JO BONDI
Attorney General
State of Florida
The Capitol, PL-01
Tallahassee, FL 32399-1050
(850) 414-3300

RUSSELL A. SUZUKI
Acting Attorney General
State of Hawaii
425 Queen Street
Honolulu, HI 96813
(808) 586-1500

THOMAS J. MILLER
Attorney General
State of Iowa
Hoover State Office Building
2nd Floor
1305 E. Walnut Street
Des Moines, IA 50319
(512) 281-5166

LAWRENCE G. WASDEN
Attorney General
State of Idaho
P.O. Box 83720
700 W. Jefferson Street
Suite 210
Boise, ID 83720-0010
(208) 334-2400

LISA MADIGAN
Attorney General
State of Illinois
100 West Randolph Street
12th Floor
Chicago, IL 60601
(312) 814-3312

MARTHA COAKLEY
Attorney General
State of Massachusetts
One Ashburton Place
Boston, MA 02108
(617) 727-2200

JANET T. MILLS
Attorney General
State of Maine
6 Station House Street
Augusta, ME 04333
(207) 626-8800

DOUGLAS F. GANSLER
Attorney General
State of Maryland
200 St. Paul Place
Baltimore, MD 21202-2021
(410) 576-6300

JIM HOOD
Attorney General
State of Mississippi
P.O. Box 220
Jackson, MS 39205
(601) 359-3680

LORI SWANSON
Attorney General
State of Minnesota
102 State Capitol
75 Rev. Dr. Martin Luther King, Jr. Blvd.
St. Paul, MN 55155-1609
(651) 296-6196

CHRIS KOSTER
Attorney General
State of Missouri
Supreme Court Building
207 W. High Street
Jefferson City, MO 65101
(573) 751-3321

STEVE BULLOCK
Attorney General
State of Montana
P.O. Box 201401
Helena, MT 59620-1401
(406) 444-2026

JON BRUNING
Attorney General
State of Nebraska
2115 State Capitol
Lincoln, NE 68509
(402) 471-2682

ROY COOPER
Attorney General
State of North Carolina
P.O. Box 629
Raleigh, NC 27602
(919) 716-6400

MICHAEL A. DELANEY
Attorney General
State of New Hampshire
33 Capitol Street
Concord, NH 03301
(603) 271-1202

GARY KING
Attorney General
State of New Mexico
111 Lomas Blvd. N.W.
Albuquerque, NM 87102
(505) 222-9000

CATHERINE CORTEZ MASTO
Attorney General
State of Nevada
100 North Carson Street
Carson City, NV 89701
(775) 684-1112

RICHARD CORDRAY
Attorney General
State of Ohio
30 E. Broad Street, 17th Fl.
Columbus, OH 43215
(614) 728-7511

W.A. DREW EDMONDSON
Attorney General
State of Oklahoma
313 N.E. 21st Street
Oklahoma City, OK 73105-4894
(405) 521-3921

JOHN R. KROGER
Attorney General
State of Oregon
1162 Court Street N.E.
Salem, OR 97301
(503) 378-6002

HENRY D. MCMASTER
Attorney General
State of South Carolina
1000 Assembly Street,
Room 519
Columbia, SC 29201
(803) 734-3970

ROBERT E. COOPER, JR.
Attorney General
State of Tennessee
P.O. Box 20207
425 Fifth Avenue North
Nashville, TN 37202-0207
(615) 741-3491

GREG ABBOTT
Attorney General
State of Texas
300 W. 15th Street
Austin, TX 78701
(512) 463-2100

MARK L. SHURTLEFF
Attorney General
State of Utah
State Capitol, Suite 230
P.O. Box 142320
Salt Lake City, UT 84114
(801) 538-9600

WILLIAM H. SORRELL
Attorney General
State of Vermont
109 State Street
Montpelier, VT 05609-1001
(802) 828-3689

ROBERT M. MCKENNA
Attorney General
State of Washington
1125 Washington Street S.E.
P.O. Box 40100
Olympia, WA 98504-0100
(360) 753-6200

DARRELL V. MCGRAW, JR.
Attorney General
State of West Virginia
State Capitol, Room 26-E
Charleston, WV 25305
(304) 558-2021

BRUCE A. SALZBURG
Attorney General
State of Wyoming
123 Capitol Building
200 W. 24th Street
Cheyenne, WY 82002
(307) 777-7841

TABLE OF CONTENTS

	Page
INTEREST OF AMICI	1
SUMMARY OF ARGUMENT	2
REASONS FOR GRANTING CERTIORARI	4
I. A Surge in Reverse Payment Agreements Is Threatening the Existence of Generic Competition and the Availability of Affordable Drugs to the States and Their Citizens	4
II. *Tamoxifen* and *Cipro* Establish Almost Conclusive Presumptions of Validity and Infringement Not Supported by Statute, Fact or Judicial Precedent	7
III. Reverse Payments Thwart Congressional Intent Behind and the Provisions of the Hatch-Waxman Act Promoting Earlier Generic Entry	15
IV. In *Cipro*, Competition was Excluded by Use of Money and Competitor Collusion, Not the Power of the Patent	18
V. Patent Rights Do Not Include the Right to Pay Competitors Not to Compete or to Collude with Competitors	21
CONCLUSION	26

TABLE OF AUTHORITIES

Page

CASES

Andrx Pharms., Inc. v. Biovail Corp., 256 F.3d 799 (D.C. Cir. 2001) 15, 21

Ark. Carpenters Health & Welfare Fund v. Bayer AG (In re Ciprofloxacin Hydrochloride Antitrust Litig.), 604 F.3d 98 (2d Cir. 2010) ..... *passim*

Bauer & Cie v. O'Donnell, 229 U.S. 1 (1913) 23

In re Bilski, 545 F.3d 943 (Fed. Cir. 2008) (*en banc*) 8

Blue Cross & Blue Shield United of Wisc. v. Marshfield Clinic, 65 F.3d 1406 (7th Cir. 1995) 24

Boston Store of Chicago v. Amer. Graphophone Co., 246 U.S. 8 (1918) 23

Brooke Group Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209 (1993) 11

Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc., 527 F.3d 1278 (Fed. Cir. 2008) 8

Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83 (1993) 9

In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003) 1, 7, 11, 19

Circuit City Stores, Inc. v. Adams, 532 U.S. 105 (2001) 17

Colorado v. Warner Chilcott Holdings Co. III, Ltd., No. 1:05-CV- 2182 (CKK), 2007 WL 6215857 (S.D.N.Y. Nov. 7, 2005) 1

TABLE OF AUTHORITIES – Continued

Page

Conn. Nat. Bank v. Germain, 503 U.S. 249 (1992) 18

Continental T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36 (1977) 12

Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752 (1984) 7

Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451 (1992) 11

eBay v. MercExchange, LLC, 547 U.S. 388 (2006) 25

FTC v. Watson Pharms., Inc., 611 F. Supp. 2d 1081 (C.D. Cal. 2009) 1

Iannelli v. United States, 420 U.S. 770 (1975) 11

Illinois Tool Works Inc. v. Indep. Ink, Inc., 547 U.S. 28 (2006) 11, 19

Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974) 8

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007) 12, 20

Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996) 13

Mercoid Corp. v. Mid-Continent Inv. Co., 320 U.S. 661 (1944) 22

Motion Picture Patents Co. v. Universal Film Mfg. Co., 243 U.S. 502 (1917) 24

New Eng. Braiding Co. v. A.W. Chesterton Co., 970 F.2d 878 (Fed. Cir. 1992) 12

TABLE OF AUTHORITIES – Continued

Page

Ohio v. Bristol-Myers Squibb Co., No. 1:02-CV-01080 (EGS), 2003 WL 21105104 (D.D.C. May 13, 2003) 1

Palmer v. BRG of Ga., Inc., 498 U.S. 46 (1990) 7

Pope Mfg. Co. v. Gormully, 144 U.S. 224 (1892) 9

Quanta Computer, Inc. v. LG Elecs., Inc., 553 U.S. 617 (2008) 22, 23

Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368 (Fed. Cir. 2006) 8

Std. Sanitary Mfg. Co. v. United States, 226 U.S. 20 (1912) 23

Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530 (Fed. Cir. 1983) 12

In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006) ..... *passim*

In re Terazosin Hydrochloride Antitrust Litig., 352 F. Supp. 2d 1279 (S.D. Fla. 2005) 1

Under Sea Indus., Inc. v. Dacor Corp., 833 F.2d 1551 (Fed. Cir. 1987) 13

United States v. Line Material Co., 333 U.S. 287 (1948) 19, 21, 23, 25

United States v. Masonite Corp., 316 U.S. 265 (1942) 19, 22, 23

United States v. New Wrinkle, Inc., 342 U.S. 371 (1952) 19

United States v. Univis Lens Co., Inc., 316 U.S. 241 (1942) 22, 24

TABLE OF AUTHORITIES – Continued

Page

Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294 (11th Cir. 2003) 11

Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398 (2004) 7

W.L. Gore & Assocs. v. Garlock, Inc., 721 F.2d 1540 (Fed. Cir. 1983) 12

Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100 (1969) 8

STATUTES

21 U.S.C. § 355(j) ..... *passim*

21 U.S.C. § 355(j)(5)(B)(iii) 15, 16

21 U.S.C. § 355(j)(5)(B)(iv) 16

21 U.S.C. § 355(j)(5)(D)(i)(V) 16

35 U.S.C. § 154(a)(1) 8

35 U.S.C. § 156 15

35 U.S.C. § 271(e)(2)(A) 16

35 U.S.C. § 282 12

LEGISLATIVE MATERIALS

148 Cong. Rec. S7348 (Jul. 25, 2002) 16

H.R. Rep. No. 98-857(I) (1984) 15

S. Rep. No. 107-167 (2002) 17

TABLE OF AUTHORITIES – Continued

Page

OTHER AUTHORITIES

Alden Abbott and Suzanne Michel, *The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation*, 46 IDEA 1 (2005) 13

Brief for Rep. Henry A. Waxman as *Amicus Curiae* Supporting Petitioner, *FTC v. Schering-Plough Corp.*, No. 05-273, 2005 WL 2462026 (11th Cir. Sept. 30, 2005) 17

California Health Care Foundation, *Health Care Almanac, Health Care Costs 101* (2010) 4

Center for Drug Evaluation and Research, U.S. FDA, *Generic Competition and Drug Prices* 5

Centers for Medicare and Medicaid Services, U.S. Dep't of HHS, *National Health Expenditures, by Source of Funds and Type of Expenditure: Calendar Years 2003-2008*, http://www.cms.gov/NationalHealthExpendData/downloads/tables.pdf. 4, 5

FTC, *Generic Drug Entry Prior to Patent Expiration* (July 2002) 13

FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (Jan. 2010) 6

C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629 (2009) 5

TABLE OF AUTHORITIES – Continued

Page

Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719 (2003) 6

Kaiser Family Foundation, *Prescription Drug Trends* (2010), http://www.kff.org/rxdrugs/upload/3057-08.pdf.....5

Paul Janicke & LiLan Ren, *Who Wins Patent Infringement Cases?*, 34 AIPLA Q.J. 1 (2006).....13

Jon Leibowitz, Comm'r, FTC, *Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-a-ck!*, at 7-8 (Apr. 26, 2006) 6

Mark A. Lemley, et al., *What to Do About Bad Patents?*, 28 Regulation 10 (Winter 2005-2006).....14

Mark A. Lemley, *Rationale Ignorance, at the Patent Office*, 95 Nw. U.L. Rev. 1495 (2001) 14

Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. Econ. 391 (2003).....6

U.S. GAO, *Intellectual Property: USPTO Has Made Progress in Hiring Examiners, but Challenges to Retention Remain* (Jun. 2005) 14

INTEREST OF AMICI[1]

The Amici States have three interests in this matter: 1) through their chief law enforcers, the Attorneys General, the States enforce federal and state antitrust laws against anticompetitive "reverse payment" agreements of the type wrongfully immunized by *Arkansas Carpenters Health & Welfare Fund v. Bayer AG* (*In re Ciprofloxacin Hydrochloride Antitrust Litigation*), 604 F.3d 98, 106-10 (2d Cir. 2010) ("*Cipro*"); 2) as *parens patriae*, the States seek to protect their consumers and businesses from anticompetitive conduct that blocks access to lower-cost generic pharmaceuticals; and 3) as their Medicaid agencies and other governmental programs are significant third-party payors for, and direct purchasers of pharmaceuticals, the States have a duty to protect their strong proprietary interest in the availability of lower-cost generic drugs.

The States have a long history of prosecuting antitrust actions where there is collusion between pharmaceutical companies to limit or exclude generic competition.[2] However, the States have limited

---

[1] All counsel of record have received ten days notice of the filing of this brief.

[2] *See, e.g.*, *FTC v. Watson Pharms., Inc.*, 611 F. Supp. 2d 1081 (C.D. Cal. 2009); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005); *Colorado v. Warner Chilcott Holdings Co. III, Ltd.*, No. 1:05-CV-2182 (CKK), 2007 WL 6215857 (S.D.N.Y. Nov. 7, 2005); *Ohio v. Bristol-Myers Squibb Co.*, No. 1:02-CV-01080 (EGS), 2003 WL 21105104 (D.D.C. May 13, 2003); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).

resources that are under additional pressures from overextended budgets. When, as here, the legal standard as to reverse payment agreements is subject to widely differing interpretations and results, State antitrust enforcers need clear guidance to fulfill their role to protect their consumers and businesses from anticompetitive agreements.

SUMMARY OF ARGUMENT

Following the Second Circuit's earlier decision in *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006) ("*Tamoxifen*"), which the *Cipro* court was duty-bound to do despite misgivings about *Tamoxifen's* soundness, *Cipro* establishes almost irrebuttable presumptions of patent validity and infringement based solely on the patent holder's untested assertions of validity and infringement. These judicially-made presumptions, subject to only minor exceptions, have no basis in law or fact, and are contrary to this Court's precedent. The presumptions, in turn, support the Second Circuit's creation of a broad immunity to the antitrust scrutiny that such collusive competitor agreements traditionally receive under this Court's rulings.

Reverse payment agreements also thwart the letter and spirit of the Drug Price Competition and Patent Term Restoration Act of 1984 ("the Hatch-Waxman Act"), 21 U.S.C. § 355(j) (2006). One of the Act's specific goals was encouraging the speedy entry

of generic competition by incentivizing litigation over and removal of weak patents that wrongly delayed generic competition.

Further, the decision below abandons common sense by attributing all the delay in generic competition to the exclusionary power of the patent. This attribution is based on the flawed assumption that the statutory privileges of a patentee include the right to collude with and pay competitors to divide up markets. Such an assumption is inconsistent with this Court's long-standing condemnation of patent licensing arrangements that go beyond the narrow monopoly rights of the patent grant, as do the reverse payment agreements, which should be treated accordingly.

As detailed in the Petition for a Writ of Certiorari ("Pet. Cert."), the approach of the Second Circuit diverges significantly from that of the Sixth and Eleventh Circuits. The Attorneys General need guidance as to the legality of reverse payment agreements that clearly eliminate generic competition and impact our States' budgets and citizens. We respectfully urge the Court to grant the Petition for a Writ of Certiorari.

REASONS FOR GRANTING CERTIORARI

I. A SURGE IN REVERSE PAYMENT AGREEMENTS IS THREATENING THE EXISTENCE OF GENERIC COMPETITION AND THE AVAILABILITY OF AFFORDABLE DRUGS TO THE STATES AND THEIR CITIZENS.

Maintaining open competition in pharmaceutical markets is critical to the States' ability to provide drugs to their consumers at a reasonable cost, and to control escalating drug costs that threaten to swamp already-strained State budgets. In 2008, State and local governments nationwide spent some $14.5 billion for drug prescriptions, while health-care spending consumed some 24% of state revenues.[3] Nationally, drug prescriptions in 2008 cost some $234 billion, more than five times the $40.3 billion spent in 1990.[4]

Brand name drugs, many of which have patent protection, account for most of the increase in the nation's burgeoning drug costs. Generic drugs, on the other hand, typically cost less than a third of the price of branded drugs, and are one of the primary

---

[3] Centers for Medicare and Medicaid Services, U.S. Dep't of HHS, *National Health Expenditures, by Source of Funds and Type of Expenditure: Calendar Years 2003-2008* (*"HHS Study"*), Table 4, http://www.cms.gov/NationalHealthExpendData/downloads/tables.pdf; California Health Care Foundation, *Health Care Almanac, Health Care Costs 101* (2010), at 11, http://www.chcf.org/~/media/Files/PDF/H/PDF%20HealthCareCosts10.pdf.

[4] *HHS Study*, *supra* note 3, at Table 2.

factors responsible for slowing the rate of increase in drug costs.[5]

Yet robust generic competition is being seriously undermined by the surge of reverse payment agreements that force States and consumers to pay monopolistic prices for branded drugs. In the instant case, Bayer enjoyed a billion dollars annually in Cipro sales. Competition from Barr[6] and other generic companies would have quickly and drastically reduced Bayer's revenues, while at the same time saving consumers hundreds of millions of dollars. By paying the generics $398 million, Bayer estimated it was able to preserve more than $1.6 billion in monopoly profits. Pet. Cert. 7. At the same time, the generics also profited handsomely from their financial pact with Bayer, making more than double what they would have made had they invalidated the Bayer patent and launched generic competition to Cipro. *Id.* at 7-8.

The aggregate financial burden of these collusive reverse payment agreements on consumers is

---

[5] Kaiser Family Foundation, *Prescription Drug Trends* (2010), at 1-3, http://www.kff.org/rxdrugs/upload/3057-08.pdf; Center for Drug Evaluation and Research, U.S. FDA, *Generic Competition and Drug Prices*, http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm.

[6] One of this case's defendants, Barr Labs, is the most frequent generic participant in reverse payment agreements, and, together with its parent, Teva, has entered into some twenty such agreements. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 656 (2009).

staggering. Studies by the Federal Trade Commission ("FTC") and prominent academics gauge the impact to be between $3.5 billion and $14 billion annually.[7]

The surge in reverse payment agreements is largely the result of the decision in *Tamoxifen*, widely viewed as sanctioning and encouraging these agreements.[8] Before that decision, patent litigation rarely settled with payments being made by the patent holders to the alleged infringers.[9] Moreover, the reverse payments made under *Tamoxifen's* protective umbrella secure generic companies' agreements to delay marketing lower-cost drugs beyond what they would agree to do in the absence of the monetary payments.[10] A recent FTC study estimates that these payments delay entry of competition for nearly 17 months relative to patent settlements lacking reverse payments.[11]

---

[7] FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, at 2 (Jan. 2010) ("FTC Recent Study"), http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf; Hemphill, *supra* note 6, at 650.

[8] *FTC Recent Study*, *supra* note 7, at 1; Jon Leibowitz, Commissioner, FTC, *Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-a-ck!*, at 7-8 (Apr. 26, 2006), http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf.

[9] Hemphill, *supra* note 6, at 638, 657.

[10] *FTC Recent Study*, *supra* note 7, at 2, 4; Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. Econ., 391, 394 (2003); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1749-63 (2003).

[11] *FTC Recent Study*, *supra* note 7, at 2, 4.

II. *TAMOXIFEN* AND *CIPRO* ESTABLISH ALMOST CONCLUSIVE PRESUMPTIONS OF VALIDITY AND INFRINGEMENT NOT SUPPORTED BY STATUTE, FACT OR JUDICIAL PRECEDENT.

It is fundamental that agreements between rivals not to compete and to allocate markets between themselves are *per se* illegal antitrust violations. *See, e.g.*, *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 49-50 (1990); *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984) ("Certain agreements, such as horizontal price fixing and market allocation, are thought so inherently anticompetitive that each is illegal *per se* without inquiry into the harm it has actually caused."). Reverse payment agreements are a species of horizontal market allocation agreements, under which competing drug companies collude and allocate 100% of the market to the branded company. *See, e.g.*, *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003) ("There is simply no escaping the conclusion that the Agreement . . . was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade."); *Tamoxifen*, 466 F.3d at 211 (recognizing the "troubling dynamic" of reverse settlements that "inevitably protect patent monopolies that are, perhaps, undeserved"). The pernicious impact on our consumers of allowing competitor collusion is self-evident. *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004)

(calling competitor collusion "the supreme evil of antitrust").

Where the generic's agreement not to compete is secured solely by the enforcement of a patent found to be valid and infringed, the competitive exclusion is within the exclusionary power of the patent, and is unobjectionable. This is because a valid patent possesses the legal power to preclude competition from an infringing generic. 35 U.S.C. § 154(a)(1); *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969) ("[P]atentee has the exclusive right to manufacture, use, and sell his invention."). Correspondingly, a patent that is invalid, unenforceable or not infringed has no exclusionary power, and thus cannot justify any exclusionary agreement between competitors. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 495 (1974) ("Congress in the patent laws decided that where no patent existed, free competition should prevail"); *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1292 (Fed. Cir. 2008) (If plaintiff's "generic drug does not infringe [defendant's] patent, then it has a right to enter the generic drug market").

It is undisputed that patents are critical to encourage and protect the massive investments required for the development and launch of new innovative drugs. *In re Bilski*, 545 F.3d 943, 1005-06 (Fed. Cir. 2008) (*en banc*) ("the pharmaceutical industry relies on patent protection in order to recoup the large sums it invests to develop life-saving and life-enhancing drugs"); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d

1368, 1383 (Fed. Cir. 2006) ("the patent system provides incentive to the innovative drug companies to continue costly development efforts").

But while valid patents are undoubtedly critical to pharmaceutical innovation, patents that are not valid or that are asserted against non-infringers can impede innovation and choke off competition from lower-priced drugs. Hence this Court has recognized that it "is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly." *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892); *see also Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100-01 (1993) (explaining the "importance to the public at large of resolving questions of patent validity").

Congress recognized that questionable patents were being used to thwart generic competition, and enacted the Hatch-Waxman Act to incentivize generic manufacturers to challenge the weak patents that thwarted generic competition. *Cipro*, 604 F.3d at 108 (Hatch-Waxman Act sought to provide an incentive for generic manufacturers to challenge presumptively valid patents, which challenges, if successful, would result in the entry of generic drugs into the market and potentially significant savings to consumers). The Hatch-Waxman Act, like our antitrust and patent laws, seeks to foster innovation and competition by recognizing and supporting valid innovative patents while, at the same time, eliminating those invalid or non-infringed patents that wrongly impede competition and innovation.

Yet despite the supreme importance of determining the true validity and scope of an asserted patent to the proper application of antitrust law and the Hatch-Waxman Act, the Second Circuit decisions have adopted a curious "bury-your-head-in-the-sand" approach to the patent's real exclusionary power. The decisions require that courts turn a blind eye to the subject, rejecting all evidence of the exclusionary scope of the patent, except in three limited instances: 1) where the infringement claims that are settled are sham and objectively baseless; 2) where the patent was obtained by fraud; or 3) where the settlement agreement imposes restrictions beyond the facial scope of the asserted patent. *Tamoxifen*, 466 F.3d at 208 ("so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly"); *id.* at 213 ("Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent."); *Cipro*, 604 F.3d at 106 ("[W]e are bound to review the *Cipro* court's ruling under the standard adopted in *Tamoxifen*.").

Thus, the Second Circuit's acceptance, without inquiry, of the "facial" asserted scope of the patent, creates what amounts to irrebuttable or conclusive presumptions of patent validity and infringement that enable anticompetitive conduct in the name of

the patent. In establishing this analytical framework, the Second Circuit expressly recognized that it would "inevitably protect patent monopolies that are, perhaps, undeserved" and that protect "weak patents." *Tamoxifen*, 466 F.3d at 211-12.

Such presumptions are not only rejected by other Circuits,[12] but have no basis in statute, fact or judicial precedent. This Court has consistently prohibited judicial creation of presumptions not based on express Congressional mandate. *See, e.g., Iannelli v. United States*, 420 U.S. 770, 790-91 (1975) ("there simply is no basis for relying on a presumption to reach a result so plainly at odds with congressional intent"); *Illinois Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 41-42 (2006) (eliminating market power presumption in light of Congressional action). In the area of antitrust, this Court has also consistently counseled against maintenance of presumptions not based upon economic analysis and actual marketplace realities. *See, e.g., Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 229 (1993) (antitrust analysis is based on market facts); *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S.

---

[12] See cases discussed at length in Pet. Cert. 13-23. *See also Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003) (court reviewed the strength of the patent at the time of the settlement agreement); *In re Cardizem*, 332 F.3d at 900 ("The Agreement whereby HMR paid Andrx $40 million per year not to enter the United States market for Cardizem . . . is *per se* illegal under the Sherman Act and under the corresponding state antitrust laws.").

451, 466-67 (1992) ("Legal presumptions that rest on formalistic distinctions rather than actual market realities are generally disfavored in antitrust law."); *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 59 (1977) (antitrust cases "must be based upon demonstrable economic effect rather than . . . formalistic line drawing").

Cipro's presumptions about patent validity and infringement subvert controlling Supreme Court precedent in a number of ways. First, there is no statutory support for the presumptions created in this case. The oft-cited statutory presumption of patent validity, 35 U.S.C. § 282, which seemingly underpins the Second Circuit's decision to make this leap (*Tamoxifen*, 466 F.3d at 209 n.22), is unavailing. The presumption of patent validity is simply a procedural device for allocating the burden of proof to an infringer, and "has no separate evidentiary value." *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983). Not only is this presumption rebuttable, but also it only applies with a full adjudication, and, thus, for example, provides no evidence that could be weighed for determining if an injunction should issue to exclude competition. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007); *New Eng. Braiding Co. v. A.W. Chesterton Co.*, 970 F.2d 878, 882 (Fed. Cir. 1992) (existence of issued patent is not evidence which can be "weighed" in determining likelihood of success for determining if injunction should issue).

Likewise, the presumption of infringement created by the *Tamoxifen/Cipro* decisions below has no statutory predicate, and also offends long-standing precedent assigning the burden of proving infringement of the asserted claims on the patentee. *See, e.g.*, *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 374 (1996); *Under Sea Indus., Inc. v. Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987) (stating that burden is always on the patentee to show infringement). Judicial creation of a new presumption of infringement by the Second Circuit decisions is unsupported and unsupportable in case and statutory law.

Moreover, the presumptions are contrary to the facts and the actual reality that many asserted patents are either invalid or not infringed. Studies of fully-litigated pharmaceutical patents found that the generics prevailed in establishing that the asserted patents were either invalid or not infringed in 70% of the cases, according to one study, and in 73% of the cases, according to another study. Paul Janicke & LiLan Ren, *Who Wins Patent Infringement Cases?*, 34 AIPLA Q.J. 1, 20 (2006); FTC, *Generic Drug Entry Prior to Patent Expiration* 1, 20 (July 2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf. The results are consistent with other studies finding that patents of all kinds challenged in litigation were held invalid in some 46% to 58% of the cases. Alden Abbott and Suzanne Michel, *The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation*, 46 IDEA 1, 11-12, n.41 and n.42 (2005).

The statistics likely reflect the reality of the patent examination process, in which examiners work on an *ex parte* basis (unlike examiners in virtually all other countries), struggle under severe budget constraints, have a backload of more than 700,000 applications, use rules skewed to favor the issuance of patents, have work quotas, and are typically allotted only 19 hours to review and finally dispose of each patent application, no matter how long or complex they might be. U.S. GAO, *Intellectual Property: USPTO Has Made Progress in Hiring Examiners, but Challenges to Retention Remain* at 5-6, 16, 25, 28 (Jun. 2005), http://www.gao.gov/new.items/d05720.pdf; Mark A. Lemley, *Rationale Ignorance, at the Patent Office*, 95 Nw. U. L. Rev. 1495, 1499 (2001). The time constraints on patent examiners prompted one prominent patent scholar's ironic observation that "the average American will spend more time watching television this week than the federal government likely spent reviewing any of the patents that made television possible." Mark A. Lemley, et al., *What to Do About Bad Patents?*, 28 Regulation 10, 10 (Winter 2005-2006).

Allowing courts to conclusively presume that patents are valid and infringed renders most, if not all, reverse payment agreements *per se* legal. The States, the Federal Trade Commission, the Department of Justice, the American Antitrust Institute and 86 professors of law or economics all agree that the decisions below in *Tamoxifen/Cipro* set a standard that is too lax, shields harmful competitor collusion,

and must be modified to permit some examination of the true confines of the patent. *In re Ciprofloxacin* (2d Cir. 2010) (Nos. 05-2851-cv(L), 05-2852-cv(CON), 05-2863-cv(CON)), Amicus Curiae Briefs supporting *en banc* review by the Second Circuit, by the 34 Attorneys General (May 20, 2010), by the United States (May 19, 2010), by the FTC (May 20, 2010), by the American Antitrust Institute (May 20, 2010) and by 86 Intellectual Property Law, Antitrust Law, Economics, and Business Professors, *et al.* (May 20, 2010).

III. REVERSE PAYMENTS THWART CONGRESSIONAL INTENT BEHIND AND THE PROVISIONS OF THE HATCH-WAXMAN ACT PROMOTING EARLIER GENERIC ENTRY.

Realization of the great savings and benefits of generic competition both to government programs and consumers inspired Congress' enactment of the Hatch-Waxman Act in 1984. H.R. Rep. No. 98-857(I) at 14, 17 (1984), reprinted in 1984 U.S.C.C.A.N. 2647. Through this Act, Congress established a regulatory structure designed to place lower-cost generic drugs in the hands of consumers at reasonable prices and to do so "fast." *Andrx Pharms., Inc. v. Biovail Corp.*, 256 F.3d 799, 809 (D.C. Cir. 2001).[13] A significant part of

---

[13] In exchange, branded drug makers received an extended patent term and the ability to trigger an automatic 30-month stay of generic competition, a power unique among patent holders. 35 U.S.C. § 156; 21 U.S.C. § 355(j)(5)(B)(iii).

the regulatory scheme recognizes that weak and dubious patents could be used to thwart generic competition, so the Act included various market incentives for generic drug makers to promptly challenge these patents. Thus, the Hatch-Waxman Act encourages a patent holder to commence patent litigation prior to the generic firm bringing its drug to market,[14] and reduces a generic entrant's potential loss in mounting the patent challenge.[15] Most importantly, the generic company is provided with a powerful financial incentive – in the form of a 180-day marketing exclusivity – to challenge weak pharmaceutical patents. 21 U.S.C. § 355(j)(5)(B)(iv) (2006).

Congress also amended the Hatch-Waxman Act in 2003 to require that reverse payment settlements be reviewed by two federal enforcement agencies, the Federal Trade Commission and Department of Justice. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. § 355(j)(5)(D)(i)(V); 148 Cong. Rec. S7348 (Jul. 25,

---

[14] The Hatch-Waxman Act deems the mere filing of a generic drug maker's Paragraph IV certification with the U.S. Food and Drug Administration ("FDA") a technical act of infringement. 35 U.S.C. § 271(e)(2)(A). To encourage patent holders to promptly file a patent infringement suit, the Hatch-Waxman Act provides a 30-month automatic stay of FDA approval to those firms that file a patent infringement action within 45 days of a Paragraph IV filing. 21 U.S.C. § 355(j)(5)(B)(iii).

[15] Under the Hatch-Waxman Act, the generic does not face damages or the loss of its investments necessary to launch a drug where it has not actually competed in the market with a generic drug. *See Tamoxifen*, 466 F.3d at 206-07.

2002) (statement of Sen. Hatch, co-author of the Hatch-Waxman Act.) ("The FTC is doing the right thing in taking enforcement actions against those who enter into anti-competitive agreements that violate our Nation's antitrust laws."). This amendment reflected Congress's view of these settlements as "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs that are intended to keep lower cost drugs off the market." S. Rep. No. 107-167, at 4 (2002). Congressman Henry Waxman, one of the principal authors of the Hatch-Waxman Act, noted that the statute was amended to "re-emphasize" the Act's "original intent of enhancing competition, not collusion, between generic and name-brand drug manufacturers." Brief for Rep. Henry A. Waxman as *Amicus Curiae* Supporting Petitioner, *FTC v. Schering-Plough Corp.*, No. 05-273, 2005 WL 2462026, at *10 (Sept. 30, 2005).

Thus, Congress, via the Hatch-Waxman Act, mandated prompt generic competition and swift patent challenges, and subjected reverse payment agreements to federal enforcers for review. Unfortunately, the *Tamoxifen/Cipro* standard adopted by the Second Circuit after the 2003 amendments renders most reverse payment agreements *per se* legal, making any antitrust review under the Act nearly meaningless except in extreme cases. This Court has cautioned that judicial decisions that render statutory provisions superfluous are disfavored. *Circuit City Stores, Inc. v. Adams*, 532 U.S. 105, 113 (2001) ("Our cases express a deep reluctance to interpret a statutory provision so as to render superfluous other provisions

in the same enactment"); *Conn. Nat. Bank v. Germain*, 503 U.S. 249, 253 (1992) ("courts should disfavor interpretations of statutes that render language superfluous").

Overturning *Tamoxifen* and *Cipro,* and permitting broader antitrust scrutiny of reverse payments would reinforce Congressional intent underlying the Hatch-Waxman Act. Doing so also would not undermine the courts' general policy of promoting settlement. Without reverse payments, patent litigants can settle, as they did in the pre-*Tamoxifen* years, with licensed entry, in which the license terms are based on the strength of the patent rather than sharing of monopoly profits. Reverse payments are not necessary to settle patent cases, and the payments "serve no obvious redeeming social purpose." *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 625 F.3d 779, 780 (2d Cir. 2010) (J. Pooler, dissenting). State antitrust enforcers have a keen interest in ensuring that generic exclusion results from the strength of the patent rather than rivals' common interest in eliminating competition and sharing the spoils at the consumers' expense.

IV. IN *CIPRO*, COMPETITION WAS EXCLUDED BY USE OF MONEY AND COMPETITOR COLLUSION, NOT THE POWER OF THE PATENT.

By their nature, reverse payments call into question precisely what the party is purchasing in exchange for the monetary payment. The court in

evaluating a reverse payment settlement must determine whether the source of the competitive exclusion is within or outside of the scope of the patent grant, because, as this Court has consistently maintained, there is no antitrust exemption for restrictions that are not plainly and fairly within the patent monopoly. *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942) (patentee cannot extend grant by contract or agreement); *United States v. New Wrinkle, Inc.*, 342 U.S. 371, 378 (1952); *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948) ("It is equally well settled that the possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly."). As the Sixth Circuit explained in *In re Cardizem*, 332 F.3d at 908 (footnote omitted), it is "one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market."

In ascertaining the source of the exclusion, as discussed above, antitrust law requires the courts to look at the reality of the practice, clearly mandating use of fact-based analysis, rather than formalistic line-drawing. *See, e.g.*, *Illinois Tool Works*, 547 U.S. at 42-43; *Continental T.V.*, 433 U.S. at 59 (antitrust cases "must be based upon demonstrable economic effect"). This Court has also repeatedly counseled the importance of using "common sense" in drawing the

boundaries of the patent grant. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 401 (2007).

It is through these prisms that the Court must address the $64,000 question, or, in this case, the $398 million question: what was the quid pro quo for the $398 million payment? Absent some explanation – and none was forthcoming here – common sense indicates that the payment secured a delay of competition not obtainable through the exclusionary power of the patent. Had the patent been strong, Bayer would not have had to pay such a huge sum to block the generics. The *Tamoxifen/Cipro* assumption that Bayer had an ironclad right to exclude the generic competitors fails to make sense of the most important economic fact in the case – the fact that Bayer made enormous payments to the generics.

The record in this case, including the settlement negotiations, confirms what common sense counsels. Bayer offered the generics two options: a small payment with only six months of generic delay, and the alternative, which the generics accepted, of a $398 million payment for six years of generic delay. Pet. Cert. 7-8. Secondly, the $398 million that Bayer paid to the generics is more than twice what the generics would have made if they had defeated the Bayer patent and competed. *Id.*

Thus, it is evident that the generics did not settle because they viewed the Bayer patent to be strong and valid. To the contrary, it is clear that they abandoned their efforts to enter the market for several

years because they were paid hundreds of millions to do so. *See Andrx Pharms.*, 256 F.3d at 813 (finding that the patentee's $10 million dollar quarterly payments to generic competitors were in return for something that the generics "would not otherwise do, that is, delay marketing of its generic"). Likewise, the exclusionary power of the Bayer patent was not viewed as sufficient to induce the generics to quit the market, so Bayer paid for the market exclusion that the patent could not provide. Thus, Barr was not exercising the power of its patent, but rather the power of $398 million to suppress competition through combination with its competitors.

V. PATENT RIGHTS DO NOT INCLUDE THE RIGHT TO PAY COMPETITORS NOT TO COMPETE OR TO COLLUDE WITH COMPETITORS.

The Second Circuit in *Tamoxifen/Cipro* incorrectly reasons that a valid patent not only includes the right to exclude through enforcement of the patent, but also to exclude through payments to rivals not to compete. *Tamoxifen*, 466 F.3d at 208-09 (by paying the generic, the brand is merely "protect[ing] that to which it is presumably entitled"). No cases from this Court support such an expansive view of the patent monopoly. To the contrary, this Court has consistently rejected patentee's efforts to expand the "narrow monopoly" of patents by engrafting ingenious "private perquisites" onto them. *Line Material*, 333 U.S. at 316-17.

The patent monopoly consists of the patentee's exclusive right to make, use and vend the invention, and it "affords no immunity for a monopoly not fairly or plainly within the grant." *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942); *United States v. Univis Lens Co., Inc.*, 316 U.S. 241, 250 (1942). Since "patents are privileges restrictive of a free economy," this Court has long required that patent rights be "strictly construed" so as "not to derogate from the general law beyond the necessary requirements of the patent statute." *Masonite*, 316 U.S. at 280. Patent rights must also be interpreted in light of the "primary purpose of our patent laws [which] is not the creation of private fortunes for the owners of patents but is to promote the progress of science and the useful arts" as directed by the Constitution under which the patent statutes are enacted. *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 626 (2008) (quotation omitted).

A patentee may vindicate its exclusive rights either through litigation or by entering license agreements. However, if the patentee does the latter, the fact that it has the right to refuse a license agreement does not mean that it can attach any conditions on the license that are not within the strict limits of the patent monopoly. *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 666 (1944) (fact that the patentee has the power to refuse a license does not enable it to enlarge the monopoly of the patent by the expedient of attaching conditions to its use); *Masonite*, 316 U.S. at 279 (while the patentee has the power to refuse a

license, he "does not have the lesser power to license on his own conditions" as there are "strict limitations" on the patentee's power).

Accordingly, this Court has consistently applied the Sherman Act to prohibit patent license agreements that extend beyond the strict exclusionary scope of the patent. For example, the Court has condemned, as outside of the exclusionary power of the patent monopoly, patent license agreements that fix the price of patented goods. *See Masonite*, 316 U.S. at 279 (agreements fixing prices for sale of patented product "secure protection from competition which the patent law unaided by restrictive agreements does not afford"); *Bauer & Cie v. O'Donnell*, 229 U.S. 1, 17 (1913) (patent grant does not include privilege to "keep up prices and prevent competition by notices restricting the price"); *Boston Store of Chicago v. Amer. Graphophone Co.*, 246 U.S. 8, 25 (1918) (resale price condition "not within the monopoly conferred by the patent law").

Patent pools that impose price limitations are also beyond the exclusionary scope of patents. *See, e.g., Line Material*, 333 U.S. at 311 (no case construes patent statute to permit patentees by cross licenses to fix prices on their respective products); *Std. Sanitary Mfg. Co. v. United States*, 226 U.S. 20, 48 (1912) (price limitations in pooled patent licenses "transcend what was necessary to protect the use of the patent"). Nor may patentees control the price or use of a patented product after its sale. *See, e.g., Quanta Computer*, 553 U.S. at 626 (the patent right is exhausted

by the sale); *Univis Lens*, 316 U.S. at 251 (patentee fixing resale prices derives no support from the patent); *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 516 (1917) (notice restricting use of machine to showing certain unpatented films is invalid because enforcement would "create a monopoly . . . wholly outside of the patent in suit and of the patent law as we have interpreted it").

The restrictions in these clearly unlawful patent license agreements suppressed competition with respect to price or use. The exclusion resulting from reverse-payment agreements is more pervasive and pernicious; it eliminates not only price competition between the competitors, but all other forms of competition between the parties. *Blue Cross & Blue Shield United of Wisc. v. Marshfield Clinic*, 65 F.3d 1406, 1415 (7th Cir. 1995) ("It would be a strange interpretation of antitrust law that forbade competitors to agree on what price to charge, thus eliminating price competition among them, but allowed them to divide markets, thus eliminating all competition among them.").

There are no cases from this Court that gives patent holders the right to exclude competition by colluding with its competitors. Such a rule would not advance the progress of science and would seriously injure the public whose interest is foremost under the patent system. Nor is there any evidence that Congress intended to provide such a right to patent holders.

A patentee that pays its competitor to abandon efforts to enter the market gets "not a benefit inherent in the right of exclusion but a benefit which flows from suppression of competition by combination with his competitors." *Line Materials*, 333 U.S. at 319. "That is more than an 'exclusive right' to an invention; it's an 'exclusive right' to form a combination with competitors." *Id.* This Court has never recognized such a right.

This Court's rulings on the rights of a patentee in litigation are similarly instructive. This Court distinguishes the patent right itself from the availability of remedies for violations of that right. Thus, in *eBay v. MercExchange, LLC*, 547 U.S. 388, 392-93 (2006), the Court found that the statutory patent rights, even of a patentee with a final adjudication of infringement, do not include the automatic right to permanently enjoin or exclude the infringing competitor. That right requires satisfaction of the traditional requirements for equitable relief and obtaining an injunction from the court. This conclusion is inconsistent with the rule of law advanced in *Cipro* that essentially allows all patentees to exclude competition by the simple expedient of paying for the exclusion.

CONCLUSION

The Attorneys General respectfully urge the Court to grant the Petition for a Writ of Certiorari in this matter.

Dated: January 7, 2011

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
MANUEL M. MEDEIROS
State Solicitor General
J. MATTHEW RODRIQUEZ
Chief Assistant Attorney General
KATHLEEN E. FOOTE
Senior Assistant Attorney General
CHERYL L. JOHNSON
Deputy Attorney General
Counsel of Record
Counsel for Amici Curiae

179

(8)

No. 10-762

In The
Supreme Court of the United States

LOUISIANA WHOLESALE DRUG CO., INC., CVS PHARMACY, INC., RITE AID CORPORATION, ARTHUR'S DRUG STORE, INC.,

Petitioners,

v.

BAYER AG, BAYER CORP., formerly doing business as Miles, Inc., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., WATSON PHARMACEUTICALS, INC., BARR LABORATORIES, INC.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit

BRIEF AMICI CURIAE OF CONSUMER FEDERATION OF AMERICA, PRESCRIPTION ACCESS LITIGATION LLP, THE NATIONAL LEGISLATIVE ASSOCIATION ON PRESCRIPTION DRUG PRICES AND U.S. PIRG IN SUPPORT OF THE PETITIONERS

DAVID A. BALTO
Counsel of Record
LAW OFFICES OF
DAVID A. BALTO
1350 I Street, NW
Suite 850
Washington, DC 20005
(202) 577-5424
david.balto@yahoo.com

MICHAEL A. CARRIER
Professor of Law
RUTGERS LAW SCHOOL-CAMDEN
217 North Fifth Street
Camden, NJ 08102

Counsel for Amici Curiae

COCKLE LAW BRIEF PRINTING CO (800) 225-6964
OR CALL COLLECT (402) 342-2831

TABLE OF CONTENTS

Page

TABLE OF CONTENTS i

TABLE OF AUTHORITIES ii

STATEMENT OF INTEREST OF AMICI CURIAE 1

SUMMARY OF ARGUMENT 4

ARGUMENT 5

I. This Court Should Grant Certiorari To Resuscitate the Text and Legislative History of the Hatch-Waxman Act 6

II. This Court Should Grant Certiorari To Ensure the Consistent Application of *Trinko* 11

III. The Court Below, Like Courts in the Federal and Eleventh Circuits, Relied on Erroneous Arguments in Creating a Rule of Near-Per Se Legality 17

IV. This Case Presents an Ideal Vehicle for the Court To Address Vital Competitive Questions 26

CONCLUSION 28

TABLE OF AUTHORITIES

Page

CASES

Arkansas Carpenters Health and Welfare Fund v. Bayer AG, 625 F.3d 779 (2d Cir. 2010) 20, 23

Credit Suisse Securities v. Billing, 551 U.S. 264 (2007) 11, 12, 13

Egyptian Goddess, Inc. v. Swisa, Inc., 543 F.3d 665 (Fed. Cir. 2008) 21

In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003) 18, 27

In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008) 17, 23, 24

In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006) .....*passim*

Lear, Inc. v. Adkins, 395 U.S. 653 (1969) 22

MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007) 21

New Eng. Braiding Co. v. A.W. Chesterton Co., 970 F.2d 878 (Fed. Cir. 1992) 21

Palmer v. BRG of Georgia, 498 U.S. 46 (1990) 15

Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005) 16, 17, 24, 25, 27

United States v. Topco Assocs., Inc., 405 U.S. 596 (1972) 15

Verizon Communications v. Law Offices of Curtis V. Trinko, 540 U.S. 398 (2004) 11

TABLE OF AUTHORITIES – Continued

Page

STATUTES

21 U.S.C. § 355(j)(2)(A)(vii) 9

21 U.S.C. § 355(j)(2)(A) 7

21 U.S.C. § 355(j)(5)(B)(iii) 8

21 U.S.C. § 355(j)(5)(F)(ii) 8

21 U.S.C. § 355(j)(8)(B) 7

35 U.S.C. § 156(c) 8

35 U.S.C. § 271(e)(1) 7

Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) 6

OTHER AUTHORITIES

130 CONG. REC. 24425 (Sept. 6, 1984) 8

130 CONG. REC. 24427 (Sept. 6, 1984) 7

148 CONG. REC. S7566 (July 30, 2002) 10

Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389 (1999) 19, 20

C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking To Preserve Drug Competition*, 109 COLUM. L. REV. 629 (2009) 3

TABLE OF AUTHORITIES – Continued

Page

C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006) 14

Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND. J. ECON. 391 (2003) 16

Community Catalyst Blog, *Senate Fix on Pay-for-Delay Vital After Court Denies Hearing*, Sept. 9, 2010, *available at* http://blog.communitycatalyst.org/index.php/2010/09/09/senate-fix-on-pay-for-delay-vital-after-court-denies-hearing 3

Cristofer Leffler & Keith Leffler, *Settling the Controversy Over Patent Settlements*, 21 RES. L. ECON. 475 (2004) 20

Federal Trade Commission, *Agreements Filed with FTC under Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005* 25

Federal Trade Commission, *Agreements Filed with FTC under Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2006* 25, 26

Federal Trade Commission, *Agreements Filed with FTC under Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2007* 25, 26

TABLE OF AUTHORITIES – Continued

Page

Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (2002) 23

Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, An FTC Staff Study* (Jan. 3, 2010) 2, 3

Generic Pharmaceuticals: Hearing No. 107-1081 Before Subcomm. on Commerce, Science, and Transportation, 107th Cong. (2002) 27

H.R. REP. NO. 98-857, pt. 1 (1984) 6, 7, 8

H.R. REP. NO. 98-857, pt. 2 (1984) 6, 8

Herbert Hovenkamp, et al., *Anticompetitive Settlements of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003) 16

Herbert Hovenkamp, et al., IP AND ANTITRUST, § 15.3 (2d ed. 2010) 14

Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F.L. REV. 11 (2004) 14

John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185 (1998) 22

Keith Leffler & Cristofer Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements*, 39 U.S.F.L. REV. 33 (2004) 20

Kimberly A. Moore, *Judges, Juries, and Patent Cases*, 99 MICH. L. REV. 365 (2000) 22

TABLE OF AUTHORITIES – Continued

Page

Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37 (2009).....*passim*

Motion of Representative Henry A. Waxman as Amicus Curiae Supporting Petitioner at *v, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006), 2005 WL 2462026 10

Patstats.org, Univ. of Houston Law Ctr. Decisions for 2000-2004, Issue Codes 1-16, 23, 24, *available at* http://www.patstats.org/2000-04.htm 22

Prepared Statement of FTC Before Subcomm. on Antitrust, Competition Policy, and Consumer Rights of Sen. Jud. Comm. (June 9, 2010).....15

Prepared Statement of FTC Before Subcomm. on Courts and Competition Policy of House Jud. Comm. (July 27, 2010), *available at* http://www.ftc.gov/os/testimony/100727antitrustoversight.pdf.....2

Thomas Rice & Karen Y. Matsuoka, *The Impact of Cost-Sharing on Appropriate Utilization and Health Status: A Review of the Literature on Seniors*, 61 MED. CARE RES. & REV. 415 (2004).....3

STATEMENT OF INTEREST OF AMICI CURIAE[1]

Amici Curiae Consumer Federation of America, Prescription Access Litigation LLC, U.S. PIRG, and National Legislative Association on Prescription Drug Prices (collectively "Amici") respectfully support Petitioners' petition for certiorari because of the concerns of skyrocketing drug costs and reduced access to affordable generic drugs.

All of the amici are public interest groups and advocates for competitive health care markets. Prescription Access Litigation LLC ("PAL") is a project of Community Catalyst, Inc., a nonprofit, nonpartisan organization building consumer and community participation in the shaping of the U.S. health system. PAL is a coalition of more than 130 consumer, labor, and community organizations in 35 states, with a combined membership of over 16 million people. The Consumer Federation of America is an association of nearly 300 nonprofit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy, and education.

---

[1] No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amici curiae or their counsel made a monetary contribution intended to fund its preparation or submission. The parties have consented to the filing of this brief and the parties have also been given at least 10 days notice of amici's intention to file.

Consumer Federation of America, www.consumerfed.org (last visited Jan. 3, 2011).

National Legislative Association on Prescription Drug Prices ("NLARx") is a national nonprofit, nonpartisan organization of state legislators who support policies to reduce prescription drug prices and expand access to affordable medicines. NLARx has promoted policies since 2000 to expand access to generic drugs and increase competition in the marketplace. U.S. PIRG, the federation of state Public Interest Research Groups ("PIRGs"), works on behalf of American consumers through public outreach to advocate for affordable health care and prescription drugs.

The Hatch-Waxman Act created incentives to challenge brand-drug patents and bring generic drugs to the marketplace sooner. Reverse-payment agreements have exactly the opposite effect. Under the agreement at issue here, Bayer paid Barr $398 million in exchange for its agreement to stay out of the market for six and a half of the remaining seven years of the ciprofloxacin ("Cipro") patent.

Few competition problems are as critical as pay-for-delay settlements such as the one involving Cipro. These agreements are currently shielding more than $20 billion of branded drugs from generic competition. Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, An FTC Staff Study*, at 2 (Jan. 3, 2010); Prepared Statement of FTC Before Subcomm. on Courts and Competition Policy of House Jud. Comm. (July 27, 2010),

at 4-5, *available at* http://www.ftc.gov/os/testimony/100727antitrustoversight.pdf.

The cost of these settlements to consumers and their health plans has been estimated at between $3.5 billion and $12 billion per year. FTC, *Pay-for-Delay;* C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking To Preserve Drug Competition*, 109 COLUM. L. REV. 629, 649 (2009).

Beyond the financial costs, these agreements have severe consequences for public health. Artificially inflated drug costs lead to high out-of-pocket costs that force patients to split pills in half or to skip taking their medications. Such consumer-coping strategies expose patients to worsening symptoms, escalating medical conditions, and even death. Thomas Rice & Karen Y. Matsuoka, *The Impact of Cost-Sharing on Appropriate Utilization and Health Status: A Review of the Literature on Seniors*, 61 MED. CARE RES. & REV. 415, 420, 427-28 (2004). Just to give one example, a pastor in Ohio with narcolepsy pays $17,000 a year to insure himself and his family. But his insurance does not cover the high price of Provigil – $650-$850 per month – forcing him to reduce or skip doses on days he "won't be driving much" so he can extend his supply of the drug. Community Catalyst Blog, *Senate Fix on Pay-for-Delay Vital After Court Denies Hearing*, Sept. 9, 2010, *available at* http://blog.communitycatalyst.org/index.php/2010/09/09/senate-fix-on-pay-for-delay-vital-after-court-denies-hearing.

Amici have a long history of advocating for access to affordable health care and for controlling costs without compromising quality. Because prescription drug spending has skyrocketed over the last decade and a half and national health expenditures on prescription drugs have quadrupled, Amici have a strong interest in the challenged settlement here, which thwarted the entry of generic ciprofloxacin into the marketplace, thereby reducing access to affordable prescription drug treatments. If the reasoning of the decision below is allowed to stand, millions of consumers will be harmed by being denied access to more affordable prescription drugs. This Court should grant Petitioners' petition for certiorari and reverse the Second Circuit's decision.

SUMMARY OF ARGUMENT

The Hatch-Waxman Act presents Congress's nuanced views on the intersection of patent and antitrust law in the pharmaceutical industry. This legislation includes multiple provisions to foster generic competition and brand-drug innovation. But a central tenet of the Act – promoting challenges to invalid patents to lower price for consumers – has been eviscerated by settlement agreements like the one at issue here. Bayer's payment of $398 million to Barr renders ineffective the central role played by generics in challenging invalid patents.

The decision by the court below, based on the precedent in *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006), repeated many of the errors on which courts in the Federal and Eleventh Circuits have relied. Four arguments, slavishly followed by the courts, have introduced the gravest mistakes: (1) settlements are beneficial, (2) patents are presumed valid, (3) reverse payments fall within the scope of the patent, and (4) reverse-payment settlements are a natural by-product of the Act. Strict adherence to these arguments flies in the face of the Hatch-Waxman Act and unnecessarily increases price and jeopardizes patients' health.

ARGUMENT

This Court should grant certiorari for three primary reasons:

(1) To resuscitate the text and legislative history of the Hatch-Waxman Act;

(2) To ensure the viability of *Trinko* in the pharmaceutical regulatory regime;

(3) To reverse the erroneous holdings of *Cipro* and other courts.

I. This Court Should Grant Certiorari To Resuscitate the Text and Legislative History of the Hatch-Waxman Act.

This Court should grant certiorari to rescue the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the Hatch-Waxman Act. Through this legislation, Congress enacted a complex regulatory regime to solve urgent problems. The marketplace in the early 1980s suffered from sparse generic entry and stifled brand-drug firm innovation.

Fostering Generic Competition. First, Congress promoted generic competition. Generic drugs have the same active ingredients and performance as brand drugs. At the time of the Hatch-Waxman Act, however, generic firms needed to undertake lengthy, expensive trials to demonstrate safety and effectiveness. FDA approval took years, and because the required tests constituted infringement, generics could not even begin the process during the patent term. At the time Congress enacted Hatch-Waxman, there was no generic on the market for 150 brand-name drugs whose patents had already expired. H.R. Rep. No. 98-857, pt. 1, at 17 (1984).

The Act's drafters lamented the "practical extension" of the patentee's "monopoly position" beyond expiration. H.R. Rep. No. 98-857, pt. 2, at 4 (1984). They sought to "make available more low-cost generic drugs." H.R. Rep. No. 98-857, pt. 1, at 14. Generic competition would save the federal and state

governments many millions of dollars each year. And given that older Americans used nearly 25 percent of prescription drugs, competition would "do more to contain the cost of elderly care than perhaps anything else this Congress has passed." H.R. Rep. No. 98-857, pt. 1, at 17; 130 Cong. Rec. 24427 (Sept. 6, 1984).

The first tool created to accelerate generic entry was the Abbreviated New Drug Application ("ANDA") process that allowed generic firms to rely on the brand drug's safety and effectiveness studies and avoid the expensive and lengthy new-drug-application process. 21 U.S.C. § 355(j)(2)(A), § 355(j)(8)(B).

Second, Congress resuscitated the experimental use defense. The Act exempted from infringement the manufacture, use, or sale of a patented invention for uses "reasonably related to the development and submission of information" under a federal law regulating the manufacture, use, or sale of drugs. 35 U.S.C. § 271(e)(1).

Third, Congress increased competition by (as discussed more fully below) creating a 180-day period of marketing exclusivity, reserved for the first generic to certify that the brand firm's patent was invalid or not infringed.

Encouraging Brand Drug Innovation. In addition to promoting generic competition, Hatch-Waxman included several mechanisms to increase incentives for brand-firm innovation.

First, Congress increased the effective patent life by extending the patent term, with the extension currently amounting to half the time the drug is in clinical trials plus the period spent awaiting FDA approval after trials. 35 U.S.C. § 156(c). Second, Congress granted an automatic 30-month stay of FDA approval to patent holders who sue Paragraph IV generic filers within 45 days. This period provides an additional exclusionary right benefiting brand firms who – even without obtaining a preliminary injunction or demonstrating entitlement to one – will not face generic competition for a substantial period of time. 21 U.S.C. § 355(j)(5)(B)(iii). Finally, Congress provided for periods of market exclusivity not based on patents, such as the four-year exclusivity period for a drug with a new active ingredient. 21 U.S.C. § 355(j)(5)(F)(ii).

The Act's drafters emphasized the equilibrium between competition and innovation. Representative Henry Waxman underscored the "fundamental balance of the bill." 130 Cong. Rec. 24425 (Sept. 6, 1984). The Energy and Commerce Committee Report explained that allowing early generic challenges "fairly balanced" the exclusionary rights of patent owners with the "rights of third parties" to contest validity and market products not covered by the patent. H.R. Rep. No. 98-857, pt. 1, at 28. And the House Judiciary Committee noted that it "has merely done what the Congress has traditionally done in the area of intellectual property law: balance the need to stimulate

innovation against the goal of furthering the public interest." H.R. Rep. No. 98-857, pt. 2, at 30.

Central Role of 180-Day Exclusivity. A central element of this equilibrium was the 180-day period of marketing exclusivity. This period was reserved for the first generic firm to successfully challenge a patent and introduce competition before the end of the patent term.

When the FDA approves a new drug application ("NDA"), it lists the drug and any relevant patents in a publication known as the Orange Book. Before entering the market, a generic applicant must provide one of four certifications for each patent listed in the Orange Book relating to the relevant NDA.

The first three certifications – no patent on the drug, an expired patent, and a promise to wait until the patent expires – do not result in periods of exclusivity. Only the "Paragraph IV" certification, by which the generic claims that the patent is invalid or not infringed, leads to exclusivity. 21 U.S.C. § 355(j)(2)(A)(vii). Given the drafters' goals to encourage entry against invalid patents before the end of the patent term, exclusivity limited to Paragraph IV makes sense.

In contrast to this straightforward purpose, settlements like the one at issue in this case have twisted the 180-day period beyond recognition. This period has morphed into a regulatory barrier to entry that allows brand drug firms to block all challenges to its patents, however weak or narrow, simply by

settling with the first-filing Paragraph IV generic. Outside this drug context, patent settlements typically involve a challenger paying a patentee to *enter* the market. Here, in contrast, brand drugs pay generics *not* to enter the market.

Drafters' disapproval of reverse-payment settlements. In the years since the passage of the Hatch-Waxman Act, the primary drafters of the legislation have expressed their disapproval of reverse-payment settlements. Representative Waxman explained that such agreements "turn[ ] the . . . legislation on [its] head." Motion of Representative Henry A. Waxman as Amicus Curiae Supporting Petitioner at *v, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006), 2005 WL 2462026. Waxman emphasized that the purpose of the legislation was to promote generic competition, not to allow generics "to exact a portion of a brand-name manufacturer's monopoly profits in return for withholding entry into the market." *Id.*

Senator Hatch similarly found such agreements "appalling." And his assessment mirrored that of Waxman in making clear that "[w]e did not wish to encourage situations where payments were made to generic firms not to sell generic drugs and not to allow multi-source generic competition." 148 Cong. Rec. S7566 (July 30, 2002).

II. This Court Should Grant Certiorari To Ensure the Consistent Application of *Trinko*.

In *Verizon Communications v. Law Offices of Curtis V. Trinko*, 540 U.S. 398 (2004), this Court articulated a powerful framework governing the intersection of antitrust and regulation. Applied to this case, the structure underscores the importance of ensuring that the antitrust analysis fits the regulatory structure of the Hatch-Waxman Act.

Application of *Trinko* to Hatch-Waxman Regulatory Regime. As this Court explained in *Trinko*, "[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue." *Id.* at 411. Courts must take "careful account" of "the pervasive federal and state regulation characteristic of the industry." *Id.* And the analysis must "recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies." *Id.*

In *Trinko*, this Court found that the Telecommunications Act of 1996 "deter[red] and remed[ied] anticompetitive harm" by requiring incumbent local exchange carriers ("ILECs"), which had state-provided monopolies in the provision of local phone service, to share their networks with competitors. *Id.* at 412.

Consistent with this approach, this Court in *Credit Suisse Securities v. Billing* concluded that the securities law regime "implicitly preclud[ed]" the

application of the antitrust laws. 551 U.S. 264, 267 (2007). Practices by which underwriting firms forced securities buyers to purchase shares, pay high commissions, and purchase less desirable securities fell "squarely within the heartland of securities regulations" that the Securities and Exchange Commission ("SEC") could, and did, supervise. *Id.* at 285.

Just as the telecommunications and securities regimes presented comprehensive frameworks, the Hatch-Waxman Act offers an exhaustive scheme that prescribed Congress's desired balance between competition and innovation in the drug industry. The drafters used patent term extensions, market exclusivity, and 30-month stays to foster innovation. And they revived the experimental use defense and created a streamlined approval process and marketing-exclusivity period to promote generic competition. Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 69 (2009). Congress' careful balance of innovation and competition in the drug industry is particularly valuable in freeing courts from the thorny task of reconciling the patent and antitrust laws.

Reverse-Payment Settlements Gutting Regime's Effectiveness. Reverse-payment settlements have blown a hole in Hatch-Waxman's effectiveness. In determining the appropriate role for antitrust enforcement, it is not just the presence of the regulatory regime that matters, but also its effectiveness. *Id.* at 70-71. For if antitrust is forced to stand down

due to an ineffective regime, there would be a significant danger of false negatives that are addressed by neither antitrust nor regulation.

The importance of a regulatory regime's effectiveness is evident in this Court's rulings. In *Trinko*, the Court explained that phone companies that provided local service were required to "be on good behavior" and not to discriminate in providing access to certain facilities before they could enter the long-distance market. 540 U.S. at 412. In addition, firms that did not satisfy these conditions were subject to financial penalties, daily or weekly reporting requirements, and the suspension or revocation of long-distance approval. *Id.* at 412-14. In *Credit Suisse*, the Court noted the SEC's active enforcement, pointing as one example to its detailed definitions of "what underwriters may and may not do and say during their road shows" and bringing actions against underwriters who violated the regulations. 551 U.S. at 277.

In contrast, in the Hatch-Waxman setting, generic firms have recently been ineffective in promoting competition through the central mechanism of patent challenges. The Act's drafters encouraged challenges to invalid patents, seeking to obtain earlier market entry and lower prices for consumers. Carrier, 108 MICH. L. REV. at 71.

Although generic entry has burgeoned in the quarter-century since Congress enacted the law, generics are increasingly not serving their designated

function. *Id.*; C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1615 (2006); Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F.L. REV. 11, 19 (2004). They are agreeing not to challenge patents and not to enter markets in exchange for payment. Many settlements even provide more money than the generic could have received by proving invalidity and noninfringement and entering the market.

The 180-day bounty, in particular, has been twisted from an incentive for the generic to challenge patents to a barrier to entry preventing challenge. By settling with the first challenger, the brand firm can significantly delay other generics' entrance into the market. *See* Herbert Hovenkamp, et al., IP AND ANTITRUST, § 15.3 at 15-45 (2d ed. 2010). Later generics would be less motivated to pursue a challenge since they would be further behind in the approval process, would not be entitled to the market exclusivity period, and would receive a return dependent on the outcome of the first filer's suit. Hemphill, *Paying for Delay*, at 1586. Such hurdles loom large given the costs of developing generic drugs, receiving FDA approval, and pursuing costly patent litigation.

In short, the Hatch-Waxman Act's carefully balanced regulatory regime is not working as intended to promote competition.

Significant Antitrust Harm of Agreements. The settling parties' usurpation of the Hatch-Waxman

regime ensures that antitrust is essential in remedying anticompetitive behavior. Antitrust's responsibility is bolstered by the severe anticompetitive dangers threatened by reverse-payment settlements. As FTC Chairman Jon Leibowitz has recently explained, "[a]greements to eliminate potential competition and share the resulting profits are at the core of what the antitrust laws proscribe." As a result, the Commission "believes strongly that these pay-for-delay settlements are prohibited under the antitrust laws." Prepared Statement of FTC Before Subcomm. on Antitrust, Competition Policy, and Consumer Rights of Sen. Jud. Comm. (June 9, 2010), at 4.

Of all the types of business activity, agreements by which competitors divide markets threaten the most dangerous anticompetitive effects. Market division restricts *all* competition between the parties on *all* grounds. Even price fixing allows the parties to compete on factors other than price.

This Court has explained that "[o]ne of the classic examples of a *per se* violation . . . is an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition." *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 608 (1972). Courts have consistently found territorial allocations among competitors to be per se illegal. In *Palmer v. BRG of Georgia*, 498 U.S. 46, 49-50 (1990), for example, this Court applied per se illegality to an agreement by which competitors divided markets, agreeing not to compete in the other's territory.

Settlement agreements by which brands pay generics not to enter the market threaten dangers similar to territorial market allocation. But instead of allocating geographic space, they allocate time, with the brand blocking all competition for a period of time. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

Uniquely Concerning Aspects of Reverse Payments. The question of market division depends on the patent's validity and infringement. These determinations are difficult to conduct in antitrust litigation. But conspicuous red flags appear in the form of substantial payments to generics not warranted by the strength of the patent. Carrier, 108 MICH. L. REV. at 73.

Assisting in the raising of the flags are the aligned incentives of the settling parties. By delaying generic entry, the brand firm increases its monopoly profits. It then uses some of these profits to pay the generic. *See, e.g.*, Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND. J. ECON. 391, 394 (2003); Herbert Hovenkamp, et al., *Anticompetitive Settlements of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1759 (2003). Sharing monopoly profits is more profitable for the brand and generic firms than competing for duopoly (and, as additional generics enter, even smaller) profits.

By contrast, other types of settlements do not align the parties' incentives as directly and can lead to more competition. One example is a traditional licensing agreement by which an alleged infringer

pays a patentee to enter the market. Such an agreement offers different incentives, with the patentee seeking higher royalties and the infringer desiring lower payments. Carrier, 108 MICH. L. REV. at 74.

In the Hatch-Waxman context, an agreement concerning the generic entry date, without any cash payment, should reflect the odds of the parties' success in patent litigation. A brand is likely to gain additional exclusivity by supplementing the parties' entry-date agreement with a payment to the generic. The *quid pro quo* for the payment would appear to be the generic's agreement to stay off the market beyond the expected entry date.

III. The Court Below, Like Courts in the Federal and Eleventh Circuits, Relied on Erroneous Arguments in Creating a Rule of Near-Per Se Legality.

The court below, like previous courts in the Second, Federal, and Eleventh Circuits, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006), *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), relied on general arguments that are inapt in the setting of the Hatch-Waxman Act.[2] These courts have taken upon

[2] The Sixth Circuit, in contrast, concluded that a reverse-payment settlement was "a horizontal agreement to eliminate competition . . . a classic example of a *per se* illegal restraint of

(Continued on following page)

themselves the Herculean task of reconciling competition and innovation. They have done this even though the legislature's preferred equilibrium appears before them on the silver platter of the Hatch-Waxman Act.

The *Tamoxifen* standard, on which the court below relied, established a much-too-permissive standard of near-per se legality. It held that "absent an extension of the monopoly beyond the patent's scope . . . and absent fraud . . . the question is whether the underlying infringement lawsuit was 'objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.'" 466 F.3d at 213. The requirement that there be sham or fraud inappropriately borrows a concept from the different setting of First Amendment petitioning (which deserves a higher bar than private agreements among rivals not to compete). The high bar warranted by the important policies fostered by petitioning is not appropriate for private, collusive arrangements among horizontal competitors not to compete.

Four arguments have introduced the gravest errors in the Second Circuit and elsewhere: (1) settlements are beneficial, (2) patents are presumed valid, (3) reverse payments fall within the scope of

---

trade." *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 908 (6th Cir. 2003).

the patent, and (4) reverse-payment settlements are a natural by-product of the Act.

"Settlements are Beneficial" Fallacy. First, courts have voiced a general policy in favor of settlement. They have recognized that settlements conserve resources, provide certainty that encourages investment, and result in licenses increasing competition. Carrier, 108 MICH. L. REV. at 60. For these reasons, the *Tamoxifen* court explained that "'courts are bound to encourage' . . . settlement[s]." 466 F.3d at 202.

But reverse-payment agreements are not typical settlements. They are agreements that dispose of the validity and infringement challenges central to the Hatch-Waxman scheme. Any general preference in the law for settlement was significantly weakened by the Act's specific framework. Carrier, 108 MICH. L. REV. at 60. A 180-day period of exclusivity for the first ANDA to challenge a patent only makes sense in the context of encouraging patent challenges. Moreover, the purpose of the exclusivity period, to ensure that a generic competitor could not "free ride" on a rival's litigation efforts before the first filer recovered litigation costs, is not promoted if the litigation never produces a judgment benefiting other generics. Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 423 (1999).

In addition, the 180-day bounty itself demonstrates the unique nature of these agreements.

General patent settlements do not prevent other competitors from challenging the patent. In these cases, even if the settling defendant agrees not to challenge the patent, many others often wait in the wings to do so. In contrast, the Hatch-Waxman bounty creates a regulatory barrier to entry that can significantly delay other patent challenges. *Id.* In short, general policies favoring settlements should give way to an industry-specific resolution that encourages patent challenges.

Finally, prohibiting exclusion payments does not undermine the general policy in favor of settlement. The patent litigants can settle via other means, such as traditional early-entry licenses. As discussed below, litigants can and do settle Hatch-Waxman cases without exclusion payments, with those payments "serv[ing] no obvious redeeming social purpose." *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, 625 F.3d 779 (2d Cir. 2010) (Pooler, J., dissenting from denial of rehearing en banc). Indeed, economists have shown that exclusion payments are not needed to achieve efficient settlements. *See* Cristofer Leffler & Keith Leffler, *Settling the Controversy Over Patent Settlements*, 21 RES. L. ECON. 475, 484-85 (2004); Keith Leffler & Cristofer Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements*, 39 U.S.F.L. REV. 33, 42 (2004).

"Patents are Presumptively Valid" Fallacy. Second, courts have upheld settlement agreements based on Section 282 of the Patent Act, which states that patents "shall be presumed valid." Courts have

relied on this presumption to determine the validity that is so crucial to deciding the appropriate antitrust treatment. The *Tamoxifen* court, for example, found that the presumption of validity allows parties to settle "weak patent cases" even though "such settlements will inevitably protect patent monopolies that are, perhaps, undeserved." 466 F.3d at 211. For five separate reasons, however, the Patent Act's presumption of validity is entitled to far less weight than courts have accorded it.

First, even if a patent is presumed to be valid, the burden of proof is always on the patentee, not the infringer, to prove infringement. *E.g.*, *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665 (Fed. Cir. 2008). In fact, courts' focus on validity has led to an insufficient recognition of the issue of infringement.

Second, the presumption is only procedural in nature. Patentees cannot, for example, rely on the presumption as substantive evidence in preliminary-injunction proceedings. *New Eng. Braiding Co. v. A.W. Chesterton Co.*, 970 F.2d 878, 882 (Fed. Cir. 1992).

Third, the presumption should be entitled to the *least* amount of deference where the parties enter agreements that prevent validity from even being challenged. Carrier, 108 MICH. L. REV. at 64. As this Court has recognized, patent litigation plays an important role in testing weak patents and ensuring that the public does not suffer the adverse effects of invalid ones. *MedImmune, Inc. v. Genentech, Inc.*, 549

U.S. 118 (2007); *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969).

Fourth, the Hatch-Waxman Act's text and legislative history demonstrate the importance of invalidity challenges. Congress's 180-day bounty to the first generic to challenge a patent's invalidity was crucial to the regime. Settlements preventing patent challenges thus are a particularly inappropriate setting for the presumption. Carrier, 108 MICH. L. REV. at 64.

Fifth, empirical studies have consistently shown that a significant percentage of granted patents are invalid. Surveys have found that:

• courts invalidated 46% of patents between 1989 and 1996, John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205 (1998);

• the alleged infringer prevailed in 42% of the patent cases that reached trial between 1983 and 1999, Kimberly A. Moore, *Judges, Juries, and Patent Cases*, 99 MICH. L. REV. 365, 385 (2000); and

• in patent cases between 2000 and 2004, courts found 43% of patents invalid and 75% not infringed, Patstats.org, Univ. of Houston Law Ctr. Decisions for 2000-2004, Issue Codes 1-16, 23, 24, *available at* http://www.patstats.org/2000-04.htm.

In the context of generic challenges in particular, the rate of invalidity is even higher. In a study of Paragraph IV challenges between 1992 and 2000, the FTC found that the generic prevailed in 73% of the

cases. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* at 16 (2002). This invalidity rate is particularly concerning, and the potential anticompetitive effects especially staggering, given the importance of the drugs that have been the subject of lawsuits. Carrier, 108 MICH. L. REV. at 65.

"Scope of Patent" Fallacy. The third argument to which courts have deferred involves the patent's scope. Courts have upheld reverse payments as a type of activity falling within the temporal scope of the patent. The court below asked whether entry-delaying settlements fell "within the scope" of the patentee's rights or whether they were "illegal market-sharing agreements." *Arkansas Carpenters*, 604 F.3d at 104. And the *Tamoxifen* court found that the settlement did not "unlawfully extend the reach" of the patent. 466 F.3d at 213; *see also Ciprofloxacin*, 544 F.3d at 1336 ("The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent.").

The concept of temporal scope, however, cannot do all the work courts require of it. The overriding question in these cases (besides infringement) is whether the patent is valid. If it is, then an agreement allowing entry before the end of the patent term is within the scope. But if the patent is not valid, it does not have any scope. For that reason, judicial inquiries into the temporal scope of the patent assume validity and thus frustrate antitrust analysis. In assuming the very validity it seeks to prove,

therefore, temporal scope is not an appropriate inquiry. Carrier, 108 MICH. L. REV. at 66.

"Natural By-Product" Fallacy. The fourth argument that some courts have accepted centers on the "natural" status of reverse payments under the Act. The *Tamoxifen* court noted that reverse payments were "particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them." 466 F.3d at 206; *see also Schering*, 402 F.3d at 1074 ("Reverse payments are a natural by-product of the Hatch-Waxman process"); *Ciprofloxacin*, 544 F.3d at 1333 n.11 ("sizable" reverse payments are a "not unexpected" occurrence under Hatch-Waxman).

Courts are correct that reverse payments have accompanied settlement agreements under the Act. But that is a far cry from a conclusion that such a development is beneficial. In fact, it may reflect no more than the parties' preference for sharing monopoly profits. To consider the point more broadly, we would not justify collusion in an industry based on rivals' effortlessly engaging in it. Similarly, the legality of reverse-payment settlements in no way depends on their frequency. Carrier, 108 MICH. L. REV. at 66-67.

Finally, as an empirical matter, reverse payments are not needed to settle disputes between brands and generics. Such payments disappear when challenged and reappear when the antitrust coast is clear. Between 1992 and 1999, 8 of the 14 final settlements

between brands and generic first-filers involved reverse payments. Federal Trade Commission, *Agreements Filed with FTC under Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005*, at 4.

In 2000, the FTC announced that it would challenge such settlements. Abbott Labs and Geneva Pharms., File No. 981-0395 (Mar. 16, 2000). In the succeeding four years, between 2000 and 2004, *not one* of 20 reported agreements involved a brand paying a generic to delay entering the market. Federal Trade Commission, *Agreements Filed with FTC under Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2006*, at 4. During this period, parties continued settling their disputes, but in ways less restrictive of competition, such as through licenses allowing early generic entry.

In 2005, after the *Schering* and *Tamoxifen* courts took a lenient view of these agreements, the reverse-payment floodgates opened. Between 2005 and 2007, 31 of 72 final settlements between brand and generic firms included such payments. *Id.*; Federal Trade Commission, *Agreements Filed with FTC under Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2007*, at 3. Equally concerning, in recent years, roughly 70 to 80 percent of settlements between brand firms and first generic filers have involved reverse payments. *Id.* at 5; FY 2006 Agreements, at 6.

In short, the court below, relying on *Tamoxifen*, together with courts in the Eleventh and Federal Circuits, relied on inappropriate arguments in upholding reverse-payment settlements. These arguments fly in the face of the Hatch-Waxman Act, and, when accepted by courts, stifle the very generic competition at the heart of the Act.

IV. This Case Presents an Ideal Vehicle for the Court To Address Vital Competitive Questions.

This case presents an ideal vehicle to remedy the anticompetitive harms presented by reverse-payment settlements. Like the earlier cases, it involves a simple, and undisputed, payment from the brand to the generic to delay entering the market.

The latest round of settlements, and the ones that would confront this Court in future cases, are more complicated. They involve agreements that the parties claim entail "independent" side deals. Brand firms have paid generics for intellectual property licenses, the supply of raw materials or finished products, and product promotion. And they have paid milestones, up-front payments, and development fees for unrelated products. FY 2007 Agreements, at 2; FY 2006 Agreements, at 4-5.

This case cleanly presents the important antitrust issues for review, allowing the Court to sidestep the potentially nettlesome question of whether the payment is for delay at all.

In 2003, a representative of the brand firms' trade association, the Pharmaceutical Research Manufacturers Association ("PhRMA"), explained to Congress that wholesale changes to the Hatch-Waxman Act were not needed. Why? Because reverse-payment cases such as *Cardizem* and *Schering-Plough* "outline facts that would have been violations of the antitrust laws and/or the patent laws whether the Hatch-Waxman Act existed or not." Generic Pharmaceuticals: Hearing No. 107-1081 Before Subcomm. on Commerce, Science, and Transportation, 107th Cong. at 71 (2002). If PhRMA itself could admit the serious antitrust concerns with these agreements, there should be no question that the rule of near-per se legality is inappropriate.

CONCLUSION

This Court should grant certiorari to reverse the court below, to give effect to the Hatch-Waxman Act, and to save consumers billions of dollars from anti-competitive settlements.

Respectfully submitted,

January 7, 2011

DAVID A. BALTO
Counsel of Record
LAW OFFICES OF
DAVID A. BALTO
1350 I Street, NW
Suite 850
Washington, DC 20005
(202) 577-5424
david.balto@yahoo.com

MICHAEL A. CARRIER
Professor of Law
RUTGERS LAW SCHOOL-CAMDEN
217 North Fifth Street
Camden, NJ 08102

Counsel for Amici Curiae

179 (7)

No. 10-762

JAN 7 - 2011

IN THE

Supreme Court of the United States

LOUISIANA WHOLESALE DRUG CO., AG, *et al.*,

Petitioners,

v.

BAYER AG AND BAYER CORP., *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF AMICI CURIAE OF 86 INTELLECTUAL PROPERTY LAW, ANTITRUST LAW, ECONOMICS, BUSINESS AND PUBLIC HEALTH PROFESSORS IN SUPPORT OF CERTIORARI

PROFESSOR MARK A. LEMLEY
Counsel of Record
STANFORD LAW SCHOOL
559 Nathan Abbott Way
Stanford, CA 94305
(650) 723-4605
mlemley@law.stanford.edu

January 7, 2011

234186

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

QUESTION PRESENTED

Whether an agreement by a patent owner to pay a potential competitor not to enter the market is legal *per se*, as the Second and Federal Circuits have held, to be treated under the rule of reason, as the Eleventh Circuit has held, or illegal *per se*, as the Sixth Circuit has held?

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
TABLE OF CONTENTS	ii
TABLE OF APPENDICES	iv
TABLE OF CITED AUTHORITIES	v
INTEREST OF THE *AMICI CURIAE*	1
REASONS FOR GRANTING THE PETITION	1
I. The Second Circuit Rule Is Unprecedented and Conflicts With the Approaches of the Sixth Circuit, the Eleventh Circuit, and the Federal Trade Commission	1
II. Exclusion Payments Are Generally Anticompetitive	6
A. The Settling Parties Have an Incentive to Preserve Monopoly Profits in Ways That Harm Consumers, Competition, and Public Health	6
B. The Second Circuit Wrongly Assumed That Every Patent Holder Has an Absolute Right to Prevent Competition	9

Table of Contents

Page

C. Permitting Exclusion Payments Is Not Necessary To Encourage Settlements in the Public Interest 12

III. This Case Presents a Question of Extraordinary Importance, and Is an Appropriate Vehicle For Addressing That Question 14

CONCLUSION 16

TABLE OF APPENDICES

APPENDIX — LIST OF SIGNATORIES 1a

TABLE OF CITED AUTHORITIES

Page

CASES

Arkansas Carpenters' Health and Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. 2010) 3

Aronson v. Quick Point Pencil Co., 440 U.S. 257 (1979) 7

Blonder-Tongue Labs. v. Univ. of Illinois Found., 402 U.S. 313 (1971) 7

In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003) 3

In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008) 3

In re Etter, 756 F.2d 852 (Fed. Cir. 1985) 9

In re Schering Plough Corp., No. 9297 (F.T.C. Dec. 18, 2003), *rev'd*, 402 F.3d 1056 (11th Cir. 2005) 3

In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006) 2, 8, 12

Cited Authorities

Page

Lear, Inc. v. Adkins,
395 U.S. 653 (1969) 7, 9, 10, 11

Palmer v. BRG of Georgia, Inc.,
498 U.S. 46 (1990) 6

Pope Manufacturing Co. v. Gormully,
144 U.S. 224 (1892) 14

Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.,
324 U.S. 806 (1945) 14

Schering Plough Corp. v. FTC,
402 F.3d 1056 (11th Cir. 2005) 5

United States v. Glaxo Group, Ltd.,
410 U.S. 52 (1973) 7

Valley Drug Co. v. Geneva Pharmaceuticals, Inc.,
344 F.3d 1294 (11th Cir. 2003) 3

Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.,
382 U.S. 172 (1965) 14

Page

OTHER AUTHORITIES

John R. Allison & Mark A. Lemley, "Empirical Evidence on the Validity of Litigated Patents," 28 *Am. Intell. Prop. L. Ass'n. Q.J.* 185 (1998) 10

Roger D. Blair & Thomas F. Cotter, "Are Settlements of Patent Disputes Illegal Per Se?," 47 *Antitrust Bull.* 491 (2002) 4

Jan Blustein, *Drug Coverage and Drug Purchases by Medicare Beneficiaries with Hypertension*, 19 Health Aff. 219 (2000) 15

Jeremy Bulow, "The Gaming of Pharmaceutical Patents," in 4 *Innovation Policy and the Economy* (Adam B. Jaffe *et al.* eds. 2004) ... 4

Michael A. Carrier, "Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality," 108 *Mich. L. Rev.* 37 (2009) 4

Daniel A. Crane, "Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications," 54 *Fla. L. Rev.* 747 (2002) 4

Joshua P. Davis, Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should Be Per Se Illegal, 41 *Rutgers L. J.* __ (forthcoming 2010) 5

Page

Joseph Farrell and Robert Merges, "Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help," 19 *Berkeley Tech L.J.* 943 (2004) 13

Joseph Farrell & Carl Shapiro, "How Strong Are Weak Patents?" 98 *Am. Econ. Rev.* (2008) ... 4

Robin Cooper Feldman, *The Role of Science in Law* 167 (Oxford 2009) 4

C. Scott Hemphill, "An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition," 109 *Colum. L. Rev.* 629 (2009) 15

C. Scott Hemphill, "Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem," 81 *NYU L. Rev.* 1553 (2006) 4

1 *H. Hovenkamp et al., IP and Antitrust* § 15.3a1[B] (2d ed. 2010) 8

1 *Herbert Hovenkamp et al., IP and Antitrust* §15.3a1(C) (2d ed. 2010) 4, 5

Herbert Hovenkamp *et al.*, "Anticompetitive Settlement of Intellectual Property Disputes," 87 *Minn. L. Rev.* 1719 (2003) 4

Page

Kaiser Family Foundation *et al.*, *National Survey on Prescription Drugs* 4 (Sept. 2000) 15

Mark A. Lemley & Carl Shapiro, "Probabilistic Patents," 19 *J. Econ. Perspectives* 75 (2005) 4

Joseph Scott Miller, "Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents," 19 *Berkeley Tech. L.J.* 667 (2004) 13

Maureen A. O'Rourke & Joseph F. Brodley, "An Incentives Approach to Patent Settlements," 87 *Minn. L. Rev.* 1767 (2003) 5

David W. Opderbeck, "Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation," 98 *Geo. L.J.* ___ (forthcoming 2010) 4

Rudolph J.R. Peritz, "Three Statutory Regimes at Impasse: 'Reverse Payments' in 'Pay-for-Delay' Settlement Agreements between Brand-Name and Generic Drug Companies," in *More Common Ground for International Competition Law?*, Josef Drexl, Warren Grimes, Rudolph J.R. Peritz, Edward Swaine, eds. (Aldershot, U.K.: Edw. Elgar Pub., 2010) 4

Cited Authorities

Page

Catherine J.K. Sandoval, "Pharmaceutical Reverse Payment Settlements: Presumptions, Procedural Burdens, and Covenants Not to Sue Generic Drug Manufacturers," 26 *Santa Clara Comp. & High Tech. L.J.* 141 (2009) 5

Carl Shapiro, "Antitrust Limits to Patent Settlements," 34 *Rand J. Econ.* 391 (2003) 4

Statement of the American Medical Association before the Subcommittee on Commerce, Trade, and Consumer Protection of the Committee on Energy and Commerce, United States House of Representatives, April 13, 2009 15

INTEREST OF THE *AMICI CURIAE*

The Academic Amici are professors who have collectively written extensively on innovation, intellectual property, competition and antitrust. We come from a variety of fields, including intellectual property law, antitrust law, economics, and business schools. Amici have no stake in the outcome of this case.[1] (A list of signatories is in Appendix A.) Our sole interest in this case is that patent and antitrust law develop in a way that serves the public interest and public health by promoting both innovation and competition.

REASONS FOR GRANTING THE PETITION

I. The Second Circuit Rule Is Unprecedented and Conflicts With the Approaches of the Sixth Circuit, the Eleventh Circuit, and the Federal Trade Commission

The precedent that compelled the outcome in this case contains fundamental errors of economic reasoning and would shield many anti-competitive agreements from the reach of antitrust law, causing great harm to competition, to U.S. consumers, and (by unjustifiably

---

1. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici curiae* or their counsel made a monetary contribution intended to fund its preparation or submission. The parties have consented to the filing of this brief and such consents are being lodged herewith. The parties have also been given at least 10 days notice of amici's intention to file.

raising the costs of needed medicines) to public health. Under the Second Circuit's decision in *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212 (2d Cir. 2006), an agreement between a patent holder and an alleged infringer to settle their patent litigation cannot violate the antitrust laws so long as the patent litigation was not a sham or otherwise baseless and the settlement agreement does not impose restrictions on the alleged infringer that extend beyond the scope of the patent. Such settlements are immune from antitrust scrutiny even if, as here, the patent holder makes a substantial payment to the alleged infringer in exchange for the latter's promise not to sell the patented product independently during the patent's lifetime, and even if the patent in question is "fatally weak." *Id.* In so holding, *Tamoxifen* adopted a rule of near per se *legality* for a naked market division scheme, a horizontal agreement that seems anticompetitive on its face.

This rule, moreover, is based on the mistaken premise that (absent fraudulent procurement) a patent grants full immunity from antitrust scrutiny for any and all anticompetitive effects within the exclusionary power of the patent. Even if the Second Circuit's understanding of the scope of antitrust immunity attaching to an unquestionably *valid* patent were correct, the patent grant itself provides only a presumption of validity. The Second Circuit rule has effectively converted that rebuttable (and oft-rebutted) presumption into an irrebuttable one. And it has done so in this case in the face of evidence – a $398.1 million payment by the patentee to the defendant to drop its validity challenge – that suggests there was good reason

for the parties to think at the time they settled the case that this particular patent was invalid.[2]

The Second Circuit rule is far outside the mainstream of judicial and academic analysis of exclusionary settlements. The Sixth Circuit considers such agreements per se *illegal*, *see In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), and the Federal Trade Commission considers them presumptively anticompetitive, *see In re Schering Plough Corp.*, No. 9297 (F.T.C. Dec. 18, 2003), *rev'd*, 402 F.3d 1056 (11th Cir. 2005), while the Eleventh Circuit applies its own modified version of the rule of reason that inquires into the underlying validity of the patent before characterizing the conduct, *see Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003). Even the Second Circuit panel in this case has questioned the Second Circuit rule. *Arkansas Carpenters' Health and Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010). Only the Federal Circuit has adopted the Second Circuit approach, and it did so in a case in which Second Circuit law applied. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008).

Similarly, although academic commentators are divided on the treatment to be accorded such settlements, they uniformly agree they should not be considered per se *legal*. Some, including some of the

---

2. In evaluating the anticompetitive effect of a settlement, the relevant question is what the parties believed about the validity of the patent at the time they entered into the settlement.

undersigned, have written that settlements involving a large payment from the patent holder to the challenger should be presumptively anti-competitive.[3] Others have argued for applying the rule of reason[4] or for per se

---

3. *See, e.g.*, 1 *Herbert Hovenkamp et al., IP and Antitrust* §15.3a1(C) (2d ed. 2010); *Robin Cooper Feldman, The Role of Science in Law* 167 (Oxford 2009); Jeremy Bulow, "The Gaming of Pharmaceutical Patents," in 4 *Innovation Policy and the Economy*, (Adam B. Jaffe et al. eds. 2004); Michael A. Carrier, "Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality," 108 *Mich. L. Rev.* 37 (2009); Joseph Farrell & Carl Shapiro, "How Strong Are Weak Patents?" 98 *Am. Econ. Rev.* (2008); C. Scott Hemphill, "Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem," 81 *NYU L. Rev.* 1553 (2006); Herbert Hovenkamp et al., "Anticompetitive Settlement of Intellectual Property Disputes," 87 *Minn. L. Rev.* 1719 (2003); Mark A. Lemley & Carl Shapiro, "Probabilistic Patents," 19 *J. Econ. Perspectives* 75 (2005); Rudolph J.R. Peritz, "Three Statutory Regimes at Impasse: 'Reverse Payments' in 'Pay-for-Delay' Settlement Agreements between Brand-Name and Generic Drug Companies," in *More Common Ground for International Competition Law?*, Josef Drexl, Warren Grimes, Rudolph J.R. Peritz, Edward Swaine, eds. (Aldershot, U.K.: Edw. Elgar Pub., 2010); Carl Shapiro, "Antitrust Limits to Patent Settlements," 34 *Rand J. Econ.* 391 (2003).

4. Daniel A. Crane, "Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications," 54 *Fla. L. Rev.* 747, 779-96 (2002); Roger D. Blair & Thomas F. Cotter, "Are Settlements of Patent Disputes Illegal Per Se?", 47 *Antitrust Bull.* 491, 534-38 (2002); David W. Opderbeck, "Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation," 98 *Geo. L.J.* ___ (forthcoming 2010).

illegality.[5] Other courts and commentators note that the antitrust analysis is more complex for settlements that generate offsetting benefits to consumers, e.g., those involving negotiated entry dates or patent licenses.[6] But none take the position adopted by the Second Circuit here – that the court need not consider the validity of the patent in the antitrust analysis of whether that patent could have excluded a generic competitor from the market, but can instead conclusively presume that validity.

The undersigned amici differ in their views on precisely what standard should be applied to judge the legality of exclusionary settlements. We need not resolve those differences in this case because we all agree that exclusionary settlements of patent lawsuits can sometimes violate the antitrust laws. The court below took the unprecedented step of concluding that exclusionary settlements can never be illegal *as a matter of law* unless the underlying lawsuit was a sham. As a result, unless the opinion is reversed case law in the

---

5. Maureen A. O'Rourke & Joseph F. Brodley, "An Incentives Approach to Patent Settlements," 87 *Minn. L. Rev.* 1767, 1781-82 (2003); Catherine J.K. Sandoval, "Pharmaceutical Reverse Payment Settlements: Presumptions, Procedural Burdens, and Covenants Not to Sue Generic Drug Manufacturers," 26 *Santa Clara Comp. & High Tech. L.J.* 141 (2009); Joshua P. Davis, Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should Be Per Se Illegal, 41 *Rutgers L. J.* __ (forthcoming 2010).

6. *Schering Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (finding that a cross-license agreement did not violate the antitrust laws); 1 *Hovenkamp et al., supra* note 2, at §7.4e3 (discussing delayed entry settlements).

Second Circuit – and perhaps in the country as a whole – will never develop to distinguish pro- and anti-competitive settlements. And businesses will lack guidance on the legality of their conduct because fundamental conflicts between the approaches of the different circuits will persist.

II. Exclusion Payments Are Generally Anticompetitive

A. The Settling Parties Have an Incentive to Preserve Monopoly Profits in Ways That Harm Consumers, Competition, and Public Health.

A monopolist and any uniquely strong or early-arriving potential entrant have a strong incentive to enter into an exclusionary settlement. The settlement preserves the monopoly and thus keeps prices and profits high. Recognizing this, antitrust law has long condemned horizontal market division schemes as illegal per se. *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990). In the Hatch-Waxman setting, where the first drug manufacturer to file a successful Abbreviated New Drug Application (ANDA) to produce a generic version of a patent pharmaceutical is entitled to a period of statutory exclusivity, the patent owner's incentive to settle with that first generic entrant is particularly great. And because the Food and Drug Administration regulates entry into the pharmaceutical market, if a generic ANDA filer agrees to leave the market it may be years before another challenger can legally arise.

The fact that the parties to the settlement can maximize their profits through a horizontal market division agreement does not mean that such a settlement is in the public interest. The extra profit the parties share comes from somewhere. In the case of an exclusionary settlement under the Hatch-Waxman Act, it comes from the pockets of consumers: users of medicines who would be able to purchase lower cost medications if the generic manufacturer's legal arguments were successful. Absent the settlement, the patent litigation might reveal that the patent was invalid or not infringed, leading to more competition and lower prices. With an exclusion payment, the pharmaceutical patentee buys assurance that its patent will not be invalidated—something the patent law alone does not give and that the Hatch Waxman Act did not contemplate. It uses some of this extra monopoly profit, obtained by avoiding what might have been a successful legal challenge, to pay off the potential competitor.

Such a settlement denies consumers the benefits of enhanced competition that Congress intended to result if the patent were found invalid or not infringed. Those benefits are not merely a windfall from abrogation of a legitimate patent. On the contrary, they result from the right to invalidate patents the government should never have issued. This Court has repeatedly emphasized the importance of encouraging challenges to weak patents. *See, e.g., United States v. Glaxo Group, Ltd.*, 410 U.S. 52, 57 (1973); *Blonder-Tongue Labs. v. Univ. of Illinois Found.*, 402 U.S. 313 (1971); *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969); *see also Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 264 (1979). Discovering the truth about the patent's validity or scope is integral to the operation

of a patent system fundamentally bound up with the public interest. The interests of consumers are given no weight at all in the Second Circuit's calculus. Nor is the public interest in testing weak patents given any weight at all.

Under *Tamoxifen*, a patent owner and potential entrant are permitted to enter into an exclusionary settlement that denies these benefits to consumers *regardless* of contemporaneous evidence about the likelihood that the patent will be found invalid or not infringed. In this case that evidence takes the form of a large exclusionary payment from the patent holder to the potential rival, likely an indication that the patent holder considered its patent to be weak. Indeed, that payment was so large ($398.1 million) that it dwarfed the profits the generic manufacturer would expect to receive from successful entry. Put another way, even if it was *absolutely certain that the patent was invalid*, the patent owner could have paid Barr $398.1 million not to invalidate the patent, and Barr would have been better off taking the money and allowing the patent to remain in force than invalidating the patent. The presence of such a payment may or may not be conclusive evidence that the patent was invalid, but it is certainly evidence that could have led a jury to find that at the time they entered into the settlement, the parties believed the patent was likely invalid.[7]

7. The district court did consider the amount in proportion to the revenue the *patentee* was making, but that is only part of the story. The share of the patentee's revenue establishes an upper bound on the likelihood of validity, but not a lower bound. *See* 1 *H. Hovenkamp et al., IP and Antitrust* § 15.3a1[B], at 15-37 to -38 (2d ed. 2010).

B. The Second Circuit Wrongly Assumed That Every Patent Holder Has an Absolute Right to Prevent Competition

By claiming to focus on the "exclusionary zone" of the patent, but ignoring the question of whether the patent was valid in the first place, the Second Circuit falls back on the *assumption* that the patent holder, by virtue of the patent grant, has an absolute right to enter into a settlement that excludes competitors from the market, simply because of the presumption of validity afforded to patents. But that assumption is false. A patent does not confer a certain legal right. While it is presumed valid, that presumption is merely a way for courts considering validity to weigh evidence, not a substantive conclusion that patents are valid. *In re Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985). Rather, it reflects an initial judgment by the Patent and Trademark Office that the invention is patentable. That judgment is made after only limited scrutiny. When a patent is asserted in litigation, accused infringers are entitled to demonstrate that the patent should not have issued. As the Court put it in *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969):

> A patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office. Moreover, the legal conclusion is predicated on factors as to which reasonable men can differ widely. Yet the Patent Office is often obliged to reach its decision in an ex parte proceeding, without the aid of the arguments which could be advanced by parties interested in proving patent invalidity. Consequently, it does not seem to us to be

> unfair to require a patentee to defend the Patent Office's judgment when his licensee places the question in issue . . .

Id. at 670. Virtually every accused infringer asserts invalidity, and nearly half of all litigated patents are ultimately found invalid.[8] The number is even higher in pharmaceutical cases – an FTC study of all pharmaceutical patent litigation between 1992 and 2000 found that the patent owner lost in 73% of the cases. http://ftc.gov/os/2006/07/P052103BarrierstoGenericEntryTestimonySenate07202006.pdf (page 10).

Further, in cases such as this one, the fact that the patent owner must pay the accused infringer a large sum of money to stay out of the market and not to challenge the patent is strong evidence that the parties to the litigation – those with the most knowledge of the facts – see the patent as likely to be held invalid or not infringed. The patent holder in such situations rationally understands that to protect the value of a monopoly to which it was never in fact entitled, it must share some of the ill-gotten revenue with those who would otherwise invalidate it. The defendants, in turn, have every incentive to settle in exchange for a share of the monopoly profits rather than to litigate. Because the generic competitor can charge only a competitive price, it is possible for a settlement to provide a share of the

---

8. John R. Allison & Mark A. Lemley, "Empirical Evidence on the Validity of Litigated Patents," 28 *Am. Intell. Prop. L. Ass'n. Q.J.* 185 (1998) (studying all patent validity litigation over an 8-year period and finding that 46% of all patents litigated to judgment were held invalid).

monopoly price profits that convey to the generic competitor even greater profits than would be achieved by a successful lawsuit. Indeed, that appears to be precisely what happened here.

The Second Circuit *per se* legality rule does not merely protect established rights of patent holders. Rather, by letting patent owners buy immunity from competition even with "fatally weak" patents, it has greatly expanded patent holders' rights, turning a rebuttable (and often-rebutted) presumption into an irrebuttable one. A presumption of validity does not entitle a patentee to evade the test of patent litigation, any more than a criminal defendant's presumption of innocence entitles him to avoid trial.

Allowing holders of weak patents thus to boost their profits is a poor way to encourage innovation, because by definition a weak patent often reflects no true innovation. And allowing them to do so by buying insulation from the very challenge that would invalidate the weak patent is perverse. This Court has recognized "the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain." *Lear*, 395 U.S. at 670. That interest would be ill-served by allowing patentees to avoid any scrutiny of the validity or scope of application of their patents simply by agreeing to split their unwarranted profits with those who would challenge their right to those profits.

C. Permitting Exclusion Payments Is Not Necessary To Encourage Settlements in the Public Interest

Tamoxifen recognized that its rule shields troubling settlements from the antitrust laws, but concluded that the policy favoring settlement is so strong that it must extend even to "fatally weak" patents, "even though such settlements will inevitably protect patent monopolies that are, perhaps, undeserved." *Tamoxifen Citrate*, 466 F.3d at 211.

We agree that there is a general policy in favor of settlement. We strongly disagree, however, with the Second Circuit's view that patent settlements must *always* be encouraged. That view confuses a general policy in favor of settlements that are in the public interest with an endorsement of a particular kind of settlement. The general preference for settlement over litigation must be tempered when settlements have important adverse effects on third parties; in the language of economics, there is no good reason to encourage settlements that impose significant negative externalities. Patent litigation serves the crucial role of testing weak patents and protecting the public from monopolies based on invalid patents. That benefit is particularly important in the context of the Hatch-Waxman Act, which exhibits a Congressional desire to encourage generic drug manufacturers to challenge pharmaceutical patents.

A successful patent challenge provides valuable (and in the case of medicines necessary) benefits to third parties, including anyone who seeks to practice the

patented technology and consumers via enhanced competition.[9] *Per se* legality undermines the important role of patent litigation in protecting the public from undeserved monopolies based on patents that may well prove to be invalid.

Reversing the Second Circuit's rule insulating cartels involving weak patents from scrutiny would by no means subject every patent settlement to an antitrust challenge. As noted above, some (including some of the undersigned) have suggested that a large exclusionary payment could be a suitable red flag, providing a limiting principle on such challenges; experience over time might suggest other approaches, but no such evolution can occur if *Tamoxifen* remains the law.

Nor is immunizing exclusion payments necessary to encourage the many settlements that are in the public interest. Both generally and in the pharmaceutical context, patent owners and generic firms can and do settle patent cases without exclusion payments, by agreeing to let the generic company enter in exchange for a license fee, by agreeing to delay entry without a payment, or in other ways that do not involve paying the generic company to forego competition. Indeed, the

---

9. *See, e.g.*, Joseph Farrell and Robert Merges, "Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help," 19 *Berkeley Tech L.J.* 943 (2004); Joseph Scott Miller, "Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents," 19 *Berkeley Tech. L.J.* 667 (2004).

Federal Trade Commission, to which pharmaceutical patent settlements must now be reported, found 14 agreements settling patent litigation during 2003 and 2004, with none involving an exclusion payment. *See* http://www.ftc.gov/opa/2005/01/drugsettlement.htm. The fact that pharmaceutical companies can and do settle litigation without exclusion payments shows that there is no need to allow anticompetitive settlements in order to get the social benefits that most settlements provide.

III. This Case Presents a Question of Extraordinary Importance, and Is an Appropriate Vehicle For Addressing That Question

This Court has long recognized that decisions on the validity of patents implicate important public interests. *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816 (1945) ("'A patent by its very nature is affected with a public interest."); *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 177 (1965); *Pope Manufacturing Co. v. Gormully*, 144 U.S. 224, 234 (1892) ("It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly."). Nowhere is that more true than in the area of pharmaceuticals. Consumers pay literally tens of billions of dollars more for patented drugs than they would for the same drugs if unpatented. Numerous studies have shown that higher drug prices result in consumers having to forego needed medicines. One study found that among people 65 and older, "a one-

dollar increase in the out-of-pocket per tablet cost resulted in the purchase of 114 fewer tablets per year."[10]

Where those patents are validly granted, the monopoly price arguably reflects a needed incentive to innovation. But where a patent owner insulates a "fatally weak" patent from judicial scrutiny by entering into an anticompetitive agreement to avoid invalidation, it is the public that bears the cost of an *improperly* obtained monopoly on needed medicines. Anticompetitive settlements of this sort are all too common, and violate the legislative purpose behind the Hatch-Waxman Act, which was in part to encourage generic manufacturers to challenge weak patents. Just ten existing pay-for-delay settlements increase the cost to consumers and the government by roughly $14 billion per year, by one estimate. C. Scott Hemphill, "An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition," 109 *Colum. L. Rev.* 629, 650 (2009). And the American Medical Association has identified pay-for-delay settlements as a significant driver of higher drug costs. Statement of the American Medical Association before the Subcommittee on Commerce, Trade, and Consumer Protection of the Committee on Energy and Commerce, United States House of Representatives, April 13, 2009.

---

10. Jan Blustein, *Drug Coverage and Drug Purchases by Medicare Beneficiaries with Hypertension*, 19 Health Aff. 219, 228 (2000); *see also* Kaiser Family Foundation et al., *National Survey on Prescription Drugs* 4 (Sept. 2000) (reporting that 9% of U.S. citizens 65 and older have had to cut down on food or other basic necessities to pay for prescription drugs), *available at* http://www.pbs.org/newshour/health/prescriptions/summaryandchartpack.pdf.

This case is an appropriate vehicle for resolving the important questions presented here. The settlement in this case is a straightforward payment to Barr to stay out of the market, in contrast to other cases in which the payments are commingled with other business relationships. The conflict among the Circuits is now clear. And pharmaceutical companies have taken the Federal Circuit's decision as a green light to enter into settlements like this. Those anticompetitive agreements will continue to proliferate unless and until the courts recognize the potential for anticompetitive harm and apply the antitrust laws accordingly. And in light of the ruling in this case, only Supreme Court review can make that happen.

CONCLUSION

We urge the Court to grant the petition for certiorari.

Respectfully submitted,

PROFESSOR MARK A. LEMLEY
Counsel of Record
STANFORD LAW SCHOOL
559 Nathan Abbott Way
Stanford, CA 94305
(650) 723-4605
mlemley@law.stanford.edu

APPENDIX

APPENDIX — LIST OF SIGNATORIES[1]

Professor Howard B. Abrams
University of Detroit-Mercy College of Law

Professor John R. Allison
McCombs Graduate School of Business
University of Texas at Austin

Professor Margo A. Bagley
University of Virginia School of Law

Professor Ann Bartow
University of South Carolina School of Law

Professor Timothy Bresnahan
Department of Economics
Stanford University

Professor Jeremy I. Bulow
Graduate School of Business
Stanford University

Professor Dan L. Burk
University of California-Irvine School of Law

Professor Darren Bush
University of Houston Law Center

Professor Irene Calboli
Marquette University Law School

1. All institutions are listed for identification purposes only.

Appendix

Professor Michael A. Carrier
Rutgers-Camden School of Law

Professor Michael W. Carroll
Washington College of Law
American University

Professor Peter Carstensen
University of Wisconsin School of Law

Professor Anupam Chander
University of California-Davis School of Law

Professor Tun-Jen Chiang
George Mason University School of Law

Professor Colleen V. Chien
Santa Clara University School of Law

Professor Andrew Chin
University of North Carolina School of Law

Professor Chester S. Chuang
Golden Gate University School of Law

Professor Ralph D. Clifford
University of Massachusetts School of Law

Professor Christopher A. Cotropia
University of Richmond School of Law

Appendix

Professor Thomas Cotter
University of Minnesota School of Law

Professor Josh Davis
University of San Francisco School of Law

Professor Stacey L. Dogan
Boston University School of Law

Professor Rochelle Dreyfuss
NYU School of Law

Professor Aaron Edlin
School of Law and Department of Economics
University of California-Berkeley

Professor Einer Elhauge
Harvard Law School

Professor Anthony T. Falzone
Stanford Law School

Professor Robin Feldman
Hastings College of the Law
University of California

Professor Eleanor Fox
NYU Law School

Professor Brett Frischmann
Benjamin N. Cardozo School of Law
Yeshiva University

Appendix

Professor Llewellyn Joseph Gibbons
University of Toledo College of Law

Professor Jim Gibson
University of Richmond School of Law

Professor Eric Goldman
Santa Clara University School of Law

Professor Thomas Greaney
St. Louis University School of Law

Professor K.J. Greene
Thomas Jefferson Law School

Professor Warren Grimes
Southwestern Law School

Professor Bronwyn H. Hall
Department of Economics
University of California at Berkeley

Professor Ward Hanson
Stanford Institute for Economic Policy Research
Stanford University

Professor C. Scott Hemphill
Columbia Law School

Professor Cynthia Ho
Loyola University-Chicago School of Law

Appendix

Professor Timothy Holbrook
Emory University School of Law

Professor Herbert Hovenkamp
University of Iowa College of Law

Professor Dan Hunter
New York Law School

Professor Mark D. Janis
University of Indiana School of Law

Professor Peter Jaszi
Washington College of Law
American University

Professor Eric E. Johnson
University of North Dakota School of Law

Professor Eileen M. Kane
Penn State Dickinson School of Law

Professor Ariel Katz
University of Toronto Faculty of Law

Professor Robert H. Lande
University of Baltimore School of Law

Professor Amy L. Landers
McGeorge Law School
University of the Pacific

Appendix

Professor Marina Lao
Seton Hall University School of Law

Professor Edward Lee
Chicago-Kent College of Law

Professor Jeffrey A. Lefstin
Hastings College of the Law
University of California

Professor Mark A. Lemley
Stanford Law School

Professor Christopher R. Leslie
University of California-Irvine School of Law

Professor Doug Lichtman
UCLA School of Law

Professor Yvette Joy Liebesman
St. Louis University School of Law

Professor Gregory N. Mandel
Temple University Law School

Professor Matt Marx
Sloan School of Management
Massachusetts Institute of Technology

Professor Jonathan Masur
University of Chicago Law School

Appendix

Professor Stephen McJohn
Suffolk University Law School

Professor Mark McKenna
Notre Dame Law School
Visiting Professor, Stanford Law School

Professor Peter S. Menell
Boalt Hall School of Law
University of California at Berkeley

Professor Michael J. Meurer
Boston University School of Law

Professor Charles Nesson
Harvard Law School

Professor Maureen A. O'Rourke
Boston University School of Law

Professor Tyler T. Ochoa
Santa Clara University School of Law

Professor David W. Opderbeck
Seton Hall Law School

Professor Kristen Osenga
University of Richmond School of Law

Professor Kevin Outterson
Schools of Law and Public Health
Boston University

Appendix

Professor Efthimios Paradisis
St. Louis University School of Law

Professor Frank Pasquale
Loftus Professor
Seton Hall Law School

Professor Rudolph J.R. Peritz
New York Law School

Malla Pollack
Co-author, Callmann on Unfair Competition, Trademarks & Monopolies

Professor Daniel B. Ravicher
Benjamin N. Cardozo School of Law
Yeshiva University

Professor R. Anthony Reese
University of California-Irvine School of Law

Professor Michael Risch
Villanova University School of Law

Professor Gregory Rosston
School of Public Policy and
Stanford Institute for Economic Policy Research
Stanford University

Professor Matthew Sag
DePaul University College of Law

Appendix

Professor Catherine Sandoval
Santa Clara University School of Law

Professor Joshua D. Sarnoff
DePaul University College of Law

Professor Kurt M. Saunders
College of Economics and Business
California State University – Northridge

Professor Brenda M. Simon
Thomas Jefferson School of Law

Professor Christopher Jon Sprigman
University of Virginia School of Law

Professor Katherine J. Strandburg
NYU School of Law

Professor Madhavi Sunder
University of California-Davis School of Law

Professor Spencer Weber Waller
Loyola University-Chicago School of Law

179

(5)

No. 10-762

Supreme Court, U.S.
FILED
JAN 6 - 2011
OFFICE OF THE CLERK

In The
Supreme Court of the United States

LOUISIANA WHOLESALE DRUG CO INC.,
CVS PHARMACY, INC., RITE AID CORPORATION,
ARTHUR'S DRUG STORE, INC.,

Petitioners,

v.

BAYER AG, BAYER CORP., formerly doing business as Miles Inc., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., WATSON PHARMACEUTICALS, INC., BARR LABORATORIES, INC.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit

BRIEF OF *AMICUS CURIAE* NATIONAL ASSOCIATION OF CHAIN DRUG STORES, INC. IN SUPPORT OF PETITIONERS

DON L. BELL, II
NATIONAL ASSOCIATION OF CHAIN DRUG STORES, INC.
413 North Lee Street
P.O. Box 1417-D49
Alexandria, VA 22313
(703) 549-3001
dbell@nacds.org

Counsel for Amicus Curiae National Association of Chain Drug Stores, Inc.

COCKLE LAW BRIEF PRINTING CO (800) 225-6964
OR CALL COLLECT (402) 342-2831

TABLE OF CONTENTS

Page

STATEMENT OF INTEREST 1

SUMMARY OF ARGUMENT 1

ARGUMENT: THE SECOND CIRCUIT'S RULING IS INCOMPATIBLE WITH FEDERAL PATENT LAW 2

CONCLUSION 8

TABLE OF AUTHORITIES

Page

CASES

Blonder-Tongue Laboratories, Inc. v. Univ. of Ill. Foundation, 402 U.S. 313 (1971) 7

Bonito Boats, Inc. v. Thundercraft Boats, Inc., 489 U.S. 141 (1989) 3, 4, 8

Cardinal Chemical Co. v. Morton Int'l, Inc., 508 U.S. 83 (1993) 6, 7

eBay Inc. v. MercExchange, LLC, 547 U.S. 388 (2006) 6

Illinois Tool Works, Inc. v. Grip-Pak, Inc., 906 F.2d 679 (Fed. Cir. 1990) 6

In re Brand Name Prescription Drugs Antitrust Litigation, 186 F.3d 781 (7th Cir. 1999) 2

In re Ciprofloxacin Hydrochloride Antitrust Litigation, 363 F. Supp. 2d 514 (E.D.N.Y. 2005) 4

In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 (2005) ..... *passim*

In re Terazosin Hydrochloride Antitrust Litigation, 352 F. Supp. 2d 1279 (S.D. Fla. 2005) 5

Lear, Inc. v. Adkins, 395 U.S. 653 (1969) 4, 7

Medimmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007) 4

Nutrition 21 v. United States, 930 F.2d 867 (Fed. Cir. 1991) 5

Precision Mfg. Co. v. Auto Maintenance Machine Co., 324 U.S. 806 (1945) 6

TABLE OF AUTHORITIES – Continued

Page

Schering-Plough Corp. v. Federal Trade Comm'n, 402 F.3d 1056 (11th Cir. 2005) 4

Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327 (1945) 7

Sola Elec. Co. v. Jefferson Elec. Co., 317 U.S. 173 (1942) 7, 8

Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530 (Fed. Cir. 1983) 5

STATUTES

35 U.S.C. § 281 4

35 U.S.C. § 282 4

STATEMENT OF INTEREST[1]

The National Association of Chain Drug Stores, Inc. ("NACDS") is a non-profit association of nearly 140 retail pharmacy chains. NACDS members operate more than 39,000 retail community pharmacies and dispense approximately 72% of Americans' prescription drugs. Anticompetitive practices by drug manufacturers, such as the practice at issue in this case, harm NACDS members and their customers by maintaining artificially high prices for prescription drugs. NACDS believes that its industry-wide perspective on this important issue will be of assistance to the Court and therefore respectfully submits this *amicus curiae* brief in support of the Petition.

SUMMARY OF ARGUMENT

The rule of decision adopted by the Second Circuit in *Tamoxifen* and applied in this case disregards this Court's patent precedents by allowing private

[1] All parties were notified ten days prior to the due date of this brief of the intention to file. All parties have consented to the filing of this brief, and their letters of consent have been filed with the Clerk of the Court. Pursuant to this Court's Rule 37.6, *amicus* states that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus* made a monetary contribution to the preparation or submission of this brief.

parties to create what is in effect a "private patent" that provides its owner with greater protection from competition than that afforded by the federal patent laws. Federal patent law, however, incorporates a policy favoring competition in the American economy except to the extent that competition is displaced by the narrow and carefully drawn legal rules that define the scope and duration of a federal patent. By allowing private patents that fall outside those legal rules, the *Tamoxifen* standard seriously undermines federal patent policy. This Court should grant certiorari to maintain the proper balance between competition and intellectual property protection.

ARGUMENT

THE SECOND CIRCUIT'S RULING IS INCOMPATIBLE WITH FEDERAL PATENT LAW

Generic entry is a critical event in the life of a branded pharmaceutical. As Judge Posner has noted, prior to entry of an AB-rated generic most "manufacturers of brand name prescription drugs . . . have market power." *In re Brand Name Prescription Drugs Antitrust Litigation*, 186 F.3d 781, 786 (7th Cir. 1999). Generic entry effectively dissipates that market power and brings the benefits of lower-priced pharmaceuticals to wholesalers, retail pharmacies and American consumers. Of course, since the savings achieved by pharmaceutical purchasers along the distribution chain come directly out of the pockets of

the branded pharmaceutical manufacturers, those manufacturers have a strong financial incentive to delay the entry of an AB-rated generic as long as possible.

In evaluating the lawfulness of the practices at issue in this case, the Second Circuit applied the legal standard adopted in a prior 2-1 panel decision of the same court. *See In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2005). While the *Tamoxifen* standard attempts to balance the societal interests in promoting economic competition and enforcing legitimate intellectual property rights, it gives too little weight to the former and too much weight to the latter. In particular, the standard applied by the Second Circuit is inconsistent with federal patent law because it disregards several critical limitations inherent in the substantive and procedural rules that make up that body of law.

The federal patent laws define not only what *is* protected by patent law, but also – and just as importantly – what is *not* protected. *See Bonito Boats, Inc. v. Thundercraft Boats, Inc.*, 489 U.S. 141, 151 (1989). Patent law itself, unaided by federal antitrust law, incorporates a federal policy favoring competition before, after and during the existence of a U.S. patent, so long as that competition falls outside the narrow and carefully limited scope of the monopoly conferred by the patent laws. This policy is strong enough to preempt state laws that purport to offer inventors protection from competition for inventions that do not qualify for protection under federal patent

law. *Id.* at 151-57. As Justice O'Connor wrote in *Bonito Boats*, the provisions of federal patent law "embody a congressional understanding, implicit in the Patent Clause itself, that *free exploitation of ideas will be the rule*, to which the protection of a federal patent is the exception." *Id.* at 151 (emphasis supplied).

The *Tamoxifen* standard threatens to make "free exploitation of ideas" the exception rather than the rule in a number of independent ways.

First, the *Tamoxifen* standard rests on the proposition that the holder of a federal patent has an absolute "right to exclude" that may be enforced by paying competitors not to compete. *See In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514, 524 (E.D.N.Y. 2005); *see also Schering-Plough Corp. v. Federal Trade Comm'n*, 402 F.3d 1056, 1066 (11th Cir. 2005). But patent law provides no such absolute right to exclude. As this Court has noted, "[a] patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office," and one "as to which reasonable men can differ widely." *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969). Contrary to the decision below, patent law provides for *judicial* determination of both patent validity and infringement, with the burden of proof imposed on the patentee to prove infringement and the burden on the alleged infringer to prove invalidity. 35 U.S.C. §§ 281, 282; *see Medimmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (federal courts have jurisdiction to decide patent validity even when the parties have

entered into a license and are complying with that license agreement). Thus, any appropriate analysis of exclusion payments must take into account the possibility that the patent being enforced will be declared invalid. *See In re Terazosin Hydrochloride Antitrust Litigation*, 352 F. Supp. 2d 1279, 1298 (S.D. Fla. 2005) ("any construction of the patent's exclusionary scope . . . that fails to take into account the chances of the patent being held invalid would essentially afford pioneer drug manufacturers an unbridled power to exclude others without regard to the strength of their patent rights").

Second, in relying on the *rebuttable* presumption of patent validity to justify exclusion payments, the *Tamoxifen* standard not only disregards the distinction between rebuttable and conclusive but also transforms a procedural device into a substantive legal right. The presumption of validity "is a procedural device, not substantive law." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983). Moreover, the presumption of validity applies only in a full adjudication on the merits. In proceedings short of full adjudication – for example, at the preliminary injunction stage – "the *patentee* carries the burden of showing likelihood of success with respect to the patent's validity." *Nutrition 21 v. United States*, 930 F.2d 867, 869 (Fed. Cir. 1991) (emphasis in original). In pharmaceutical as well as other patent cases, courts applying patent law frequently deny preliminary injunctions on the ground that, at least until a court has ruled on validity and infringement, the

alleged infringer has a "right to compete." *See, e.g., Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 684 (Fed. Cir. 1990).

Third, the *Tamoxifen* standard assumes that a finding of validity and infringement automatically results in a judicially enforceable order excluding the infringer from competing. In fact, even after a court has entered a final judgment finding infringement, the patentee is not automatically entitled to exclude the infringer, but instead must satisfy the traditional requirements for injunctive relief. *See eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006).

Fourth, the *Tamoxifen* standard disregards the fact that, because patent enforcement imposes costs on society in the form of monopoly rents, there is a public interest in judicial determination of patent validity that is absent or greatly muted in other areas of the law. As the Supreme Court has emphasized, "[a] patent by its very nature is affected with a public interest" because of its potentially "far-reaching social and economic consequences." *Precision Mfg. Co. v. Auto Maintenance Machine Co.*, 324 U.S. 806, 816 (1945). As a result, the Court has adopted rules that reduce the likelihood that invalid patents will be enforced.

For example, in *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83 (1993), the Court disapproved the Federal Circuit's practice of vacating a district court declaration of patent invalidity once the Court of Appeals affirmed a finding of non-infringement.

The Court noted that "'of the two questions [validity and infringement], validity has the greater public importance,'" and that a court follows the "'better practice by inquiring fully into the validity of [the] patent.'" *Id.* at 100 (quoting *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 330 (1945)). Likewise, in *Blonder-Tongue Laboratories, Inc. v. Univ. of Ill. Foundation*, 402 U.S. 313 (1971), the Court ruled that a finding of patent invalidity in one case collaterally estops the patent holder from relitigating the issue in a subsequent case against a different defendant, despite the fact that a finding of patent *validity* has no such preclusive effect, because "the opportunity to relitigate might, as a practical matter, grant monopoly privileges to the holders of invalid patents." *Cardinal Chemical*, 508 U.S. at 101. And in *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), the Court held that federal patent law preempted a rule of state contract law providing that a patent licensee cannot raise the invalidity of the patent as a defense in an action for unpaid royalties. The Court relied on the principle that "federal law requires, that all ideas in general circulation be dedicated to the common good unless they are protected by a valid patent." *Id.* at 668.

Even before *Lear* was decided, this Court created an exception to the doctrine of patent licensee estoppel in cases where the licensee alleged that the license violated the Sherman Act. *See Sola Elec. Co. v. Jefferson Elec. Co.*, 317 U.S. 173 (1942). In *Sola*, the Court ruled that, as a matter of federal law, the licensee *must* be permitted to raise patent invalidity

as a defense in an action to enforce a license agreement alleged to be unlawful under the antitrust laws because "[a]greements fixing the competitive sales price of articles moving interstate, not within the protection of a [valid] patent, are . . . prohibited by the Sherman Act." *Id.* at 176.

In each of these four respects, the *Tamoxifen* standard magnifies the branded manufacturer's rights beyond those it actually enjoys under federal patent law. It thereby contravenes the federal policy in favor of competition embodied in that law.

CONCLUSION

In *Bonito Boats*, this Court ruled that the State of Florida could not constitutionally create patent-like intellectual property rights broader than the limited and carefully delineated rights embodied in federal patent law. The Court ruled that "state regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws." 489 U.S. at 152. Yet the *Tamoxifen* standard allows *private parties* to do precisely what the State of Florida is constitutionally prohibited from doing.

The Petition should be granted.

Respectfully submitted,

DON L. BELL, II
NATIONAL ASSOCIATION OF
CHAIN DRUG STORES, INC.
413 North Lee Street
P.O. Box 1417-D49
Alexandria, VA 22313
(703) 549-3001
dbell@nacds.org

Counsel for Amicus Curiae
National Association of
Chain Drug Stores, Inc.

179 (2)

No. 10-762

Supreme Court, U.S.
JAN 7 - 2011
OFFICE OF THE CLERK

In The

Supreme Court of the United States

LOUISIANA WHOLESALE DRUG CO., INC., *et al.*,

Petitioners,

v.

BAYER AG, *et al.*,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit

BRIEF OF THE PUBLIC PATENT FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

DANIEL B. RAVICHER
Counsel of Record
PUBLIC PATENT FOUNDATION, INC.
BENJAMIN N. CARDOZO SCHOOL OF LAW
55 Fifth Avenue, #928
New York, New York 10003
(212) 790-0442
ravicher@yu.edu

Counsel for Amicus Curiae

January 7, 2011

COCKLE LAW BRIEF PRINTING CO (800) 225-6964
OR CALL COLLECT (402) 342-2831

TABLE OF CONTENTS

Page

TABLE OF CONTENTS i

TABLE OF AUTHORITIES ii

INTEREST OF THE *AMICUS CURIAE* 1

SUMMARY OF ARGUMENT 2

REASONS FOR GRANTING THE PETITION 4

I. PATENT QUALITY IS A CRITICAL PUBLIC INTEREST, AND WILL SUFFER IF PATENT HOLDERS CAN PAY OFF CHALLENGERS TO THEIR PATENTS 5

A. Patent Quality In The United States Today Is Extremely Poor 5

B. Undeserved Patents Cause Substantial Public Harm 8

C. Challenges To Undeserved Patents Must Be Encouraged 10

CONCLUSION 14

TABLE OF AUTHORITIES

Page

CASES

Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368 (Fed. Cir. 2001).....9

Eli Lilly & Co. v. Barr Labs., 251 F.3d 955 (Fed. Cir. 2001).....9

Kloster Speedsteel AB v. Crucible, Inc., 793 F.2d 1565 (Fed. Cir. 1986).....12, 13

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007).....11

Lear v. Adkins, 395 U.S. 653 (1969).....12

Pope Mfng. Co. v. Gormully, 144 U.S. 224 (1892).....12

STATUTES

35 U.S.C. § 312 7

OTHER AUTHORITIES

John R. Allison, Mark A. Lemley, Kimberly A. Moore & R. Derek Trunkey, *Valuable Patents*, 92 Georgetown Law Journal 435 (2004) 6

Ex Parte Reexamination Filing Data – June 30, 2009, USPTO, www.uspto.gov/web/patents/documents/ex_parte.pdf.....7

Lara J. Glasgow, Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?, 41 IDEA 227 (2001).....13

TABLE OF AUTHORITIES – Continued

Page

H. Rep. No. 98-857(I) 13

Inter Partes Reexamination Filing Data – June 30, 2009, USPTO, www.uspto.gov/web/patents/documents/inter_partes.pdf 6, 7

Paul H. Jensen, Alfons Palangkaraya & Elizabeth Webster, *Disharmony in International Patent Office Decisions*, 16 Fed. Cir. B.J. 679 (2006) 8

Cecil D. Quillen, Ogden D. Webster, and Richard Eichman, *Continuing Patent Applications and Performance at the U. S. Patent and Trademark Office-Extended*, 12 Fed. Cir. B.J. 35 (2002) 8

Univ. of Houston Law Ctr. Inst. for Intellectual Prop. & Info. Law, Full Calendar Year 2009 Report, http://www.patstats.org/2009_full_year_posting.htm 5

INTEREST OF THE *AMICUS CURIAE*[1]

The Public Patent Foundation ("PUBPAT") is a not-for-profit legal services organization affiliated with the Benjamin N. Cardozo School of Law that aims to protect freedom in patent system. Specifically, PUBPAT represents the public interest against undeserved patents and unsound patent policy. PUBPAT has argued for sound patent policy before this Court, the Courts of Appeals for the Second, Eleventh and Federal Circuits, both houses of Congress, the U.S. Patent & Trademark Office (PTO), the United Nations, the European Union Parliament, the Australian Parliament, and many other national and international bodies. PUBPAT has also successfully challenged specific undeserved patents causing significant harm to the public through litigation and administrative proceedings. These accomplishments have established PUBPAT as a leading provider of public service patent legal services and one of the loudest voices advocating for comprehensive patent reform.

PUBPAT has an interest in this matter because the decision of this Court will have a significant effect

---

[1] In accordance with Supreme Court Rule 37.6, *Amicus Curiae* states that: (1) no counsel to a party authored this brief, in whole or in part; and (2) no person or entity, other than *amicus*, their members and counsel have made a monetary contribution to the preparation or submission of this brief. Parties were timely informed of the intent to file this *amicus* brief, and the written consents of the parties to the filing of this brief have been filed with the Clerk of the Court pursuant to Supreme Court Rule 37.3.

on the public interest represented by PUBPAT. More specifically, PUBPAT has an interest in ensuring that patent holders are not allowed to undermine patent quality by paying competitors to drop challenges to their patents. Although technically an antitrust case, this matter involves the settlement of patent infringement litigation where the challenger had mounted a legitimate attack on the validity of the subject patent. The Court of Appeals below assumed that the patent – and in fact all patents – are valid, which is completely out of touch with reality. In truth, about half of all patents challenged in court are proven invalid and the PTO's own statistics concede that more than 90% of all issued patents have substantial questions regarding their validity.

As such, PUBPAT believes its brief, authored by a registered patent attorney and professor of patent law, addressing some of the underlying patent issues in this case provides the Court with relevant legal and factual information that may not otherwise be brought to its attention. This is especially true since PUBPAT has particular experience with issues relating to patent quality.

SUMMARY OF ARGUMENT

Patent quality is the single most important issue in our patent system, because without it, our patent system risks losing all credibility and the support of the American people. We must, above all other goals,

ensure only deserving patents are issued and maintained. Thus, it should be more than plainly obvious that allowing patent holders to pay competitors to drop challenges to patents harms the public interest by eliminating one of the most important checks our American patent system has on patent quality, namely the challenging of important patents by commercially motivated parties. As such, patent holders should not be allowed to settle cases involving challenges to their patents with a substantial payment to the challenger of the patent in order to have the challenge withdrawn. In fact, encouraging challenges to patents that are of undeserved scope is a critical public service function and limits the government restraint of freedom embodied in a patent. This is a principle long recognized by this Court and adopted by Congress in passing the Hatch-Waxman scheme at the heart of this case.

Therefore, to protect the public from undeserved patents and anti-competitive settlements of patent infringement litigation whereby a potential competitor is offered a share of the monopoly profits that can be maintained if it drops its challenge to a patent and agrees to stay off the market, this Court should grant the petition for a writ of certiorari and correct the mistake made by the Second Circuit in this case.

REASONS FOR GRANTING THE PETITION

People unfamiliar with the patent system, including specifically the Court of Appeals in this case, are woefully unaware of the pathetic state of American patent quality. As a result, most people unfamiliar with the patent system tend to give patents entirely way too much credit. Rather than being rock-solid undeniable fortresses of legal dominance over a segment of technology, patents today give their owner nothing more than, at best, a fifty-fifty chance of having any exclusionary power at all. As such, the Court of Appeals' assumption that any patent has an exclusionary power equal to its full term over any product is without merit.

Instead of recognizing this fundamental truth of the patent system, the Court of Appeals instead chose to blindly adopt the position that all patents are to be presumed to have total exclusionary power over any product against which they are asserted for their entire term and, thus, any settlement of a patent infringement allegation that allows an accused product to enter the market prior to the patent's expiration is exempt from the competition laws. This conclusion is wrong and, if left undisturbed, will lead to substantial harm being caused to the American public through lower patent quality and reduced competition. To be sure, this effect will be felt not only in the pharmaceutical industry, but in many other industries as well. As such, the petition for a writ of *certiorari* should be granted.

I. PATENT QUALITY IS A CRITICAL PUBLIC INTEREST, AND WILL SUFFER IF PATENT HOLDERS CAN PAY OFF CHALLENGERS TO THEIR PATENTS

A. Patent Quality In The United States Today Is Extremely Poor

There are several sources to help determine the current level of quality for U.S. patents, and all of them paint a very clear picture that patent quality today in America is extremely poor. One source, an ongoing project of the University of Houston Law School, which is known for having one of the most reputable patent departments in the country, tracks the results of patent litigation and empirically categorizes those results according to the specific issues involved with each case. Patstats, available at www.patstats.org. Looking at their data shows that approximately 45% of all issued patents reviewed by courts in 2009 were found to have been undeserved. *See* Univ. of Houston Law Ctr. Inst. for Intellectual Prop. & Info. Law, Full Calendar Year 2009 Report, http://www.patstats.org/2009_full_year_posting.htm.

When looking at this data, there are some caveats to keep in mind. First, it could be argued that the rate at which patents asserted in litigation are determined to be invalid is not applicable to the general pool of all issued patents, since only about 1% of issued patents end up getting litigated to a decision on their merits. While this may be a valid point, it does not mean that the actual validity rate of issued patents is higher or lower than that of litigated

patents, because it is generally only the patent owner who can put a patent in litigation. Therefore, many issued patents do not get their validity challenged in litigation because the patent owner chooses not to assert the patent.

Second, even if these statistics are limited to just litigated patents, they are still extremely important because litigated patents tend to have a much greater significance to the public, on average, than non-litigated patents. John R. Allison, Mark A. Lemley, Kimberly A. Moore & R. Derek Trunkey, *Valuable Patents*, 92 Georgetown Law Journal 435 (2004). To draw an analogy, if 45% of the people on death row who challenged their convictions were actually proven innocent, that wouldn't necessarily mean that 45% of all people on death row, much less 45% of all convicted criminals, were actually innocent (that ratio could be higher or lower), but the severity of each mistake regarding someone on death row is extreme nonetheless. Similarly, the technology involved with litigated patents is almost without exception extremely valuable, so any mistakes regarding the validity of those patents can cause severe harm in and of itself, regardless of the validity rate of issued patents overall.

Another source of information about patent quality is the PTO's own statistics relating to reexamination, which show that more than 90% of all requests for reexamination are granted, an action that requires a finding that a "substantial new question of patentability" exists. *Inter Partes Reexamination Filing Data –*

June 30, 2009, USPTO, www.uspto.gov/web/patents/documents/inter_partes.pdf ("*Inter Partes* Report") (95% of all requests for *inter partes* reexamination granted); *Ex Parte Reexamination Filing Data – June 30, 2009*, USPTO, www.uspto.gov/web/patents/documents/ex_parte.pdf ("*Ex Parte* Report") (92% of all requests for *ex parte* reexamination granted); 35 U.S.C. § 312. These statistics show that the overwhelming majority of patents issued by the PTO have "questionable" validity. Our patent office may not be a rubber stamp *per se*, but it is pretty close to one in reality.

Looking deeper, the PTO's data shows that 95% of patents challenged through the *inter partes* reexamination process, which allows for ongoing participation by the challenger, are canceled or changed, while more than 75% of patents challenged through the *ex parte* reexamination process, which does not allow the challenger to participate after submitting the initial request, have their claims canceled or changed. *Inter Partes* Report (all claims canceled 60%, claims changed 35%); *Ex Parte* Report (all claims cancelled 11%, claims changed 64%). This is absolutely disgusting. Our patent system should be ashamed that it has been perverted to the point of producing patents with such low quality. The American people deserve better.

One way to confirm how grim the state of affairs is for U.S. patent quality is to compare our system's patent application outcomes to those of other well respected patent offices. Firstly, the USPTO ultimately grants patents from 85% of all original applications,

while that rate is only 64% in Japan. Cecil D. Quillen, Ogden D. Webster, and Richard Eichman, *Continuing Patent Applications and Performance at the U. S. Patent and Trademark Office-Extended*, 12 Fed. Cir. B.J. 35 (2002). However, a better comparative picture is drawn by a study of roughly 70,000 issued U.S. patents and their corresponding foreign applications, which found that counterparts to patent applications issued in the U.S. were only issued by the European Patent Office 72.5% of the time and by the Japan Patent Office only 44.5% of the time. Paul H. Jensen, Alfons Palangkaraya & Elizabeth Webster, *Disharmony in International Patent Office Decisions*, 16 Fed. Cir. B.J. 679 (2006). This evidence shows that the U.S. Patent Office is indeed granting a very disproportionally high number of patents and not implementing procedures to ensure patent quality to the same level as other developed nations. For one, most of the world permits the filing of pre-grant oppositions to patent applications by members of the public. We have no such procedure here in America, where pre-grant oppositions are expressly banned.

B. Undeserved Patents Cause Substantial Public Harm

Patents that are undeserved can cause substantial harm to the American public, because an issued patent – regardless of its true legitimacy – can be used to threaten and impede otherwise permissible, socially desirable, conduct. The threat of having to incur the costs and potential liability of a patent

lawsuit is one that few individuals or small businesses can withstand, even if the patent is of doubtful validity. This chilling effect, when caused by a patent that would be ruled invalid if challenged, provides no social benefit to the American people, because the patent contains nothing new; its invalidity means that whatever it claims or describes was either already known or was obvious in light of what was already known. This effect can be devastating to the American people.

For example, there have been several patents that were used to preclude competition in markets worth billions of dollars that were later proven to be undeserved. *See, e.g., Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368 (Fed. Cir. 2001) (patent preventing competition to $1.6B per year cancer treatment, Taxol, proven invalid); *Eli Lilly & Co. v. Barr Labs.*, 251 F.3d 955 (Fed. Cir. 2001) (patent barring alternatives to $2.9B per year antidepressant medication, Prozac, proven invalid). Poor patent quality is also partially to blame for the intensive increase in patent litigation, the dramatically higher cost of patent litigation, and the rapid rise of patent speculators – mostly contingency fee patent litigators – who are more than willing to assert questionable patents against large and small commercial actors for the chance of reaping windfall judgments.

Further, the over-patenting that results from low patent quality leads to thickets of patents that choke first inventors with countless small improvement patents claimed by others. In what is akin to

grade-inflation, by granting too many people too many patents, those inventors who legitimately did derive wonderful new technology get less credit than they deserve because of all the other patents that are issued in the related field. This results in less incentive for the truest of innovators amongst us and instead encourages investments in making minor improvements to the inventions of others. These are, unfortunately, but a few of the many harmful effects that poor patent quality is having on the American public today.

C. Challenges To Undeserved Patents Must Be Encouraged

Patents are, by nature, government-granted restraints on freedom. Every Tuesday (the day of the week the Patent Office issues new patents) there are roughly 4,500 new things that no American is allowed to do, and there is no fair use defense to patent infringement like with copyright and trademark. Thus, only those who love big government and the meddling of Washington bureaucrats into the lives and affairs of American citizens and American businesses can inherently want a bigger, stronger patent system. Thomas Jefferson, the founder of our patent system, was right to be skeptical of patents when he labeled them a necessary evil which must be short-lived and strictly limited to only those few situations when they are absolutely necessary.

Aligned with this cautious perspective on patents, this Court has repeatedly recognized that maintaining high patent quality is of the utmost importance in ensuring that the patent system benefits the American people. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007) ("[T]he results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts.") (citing U.S. Const., art. I, § 8, cl. 8). Undeserved patents substantially harm the public by imposing the high costs of exclusive rights without providing any corresponding advance in the state of the art. The public bears the burden of the chilling effect of meritless patents without receiving any commensurate benefit upon their expiration. Invalid patents pose a dead-weight economic loss for society, not to mention the inhibition on any civil liberties that may be intertwined with the unjustifiably claimed technology.

Commercial entities are frequently the best suited and most incentivized to challenge patents held by their competitors. Thus, allowing patent holders to bribe competitors to not challenge their patents most assuredly results in a decrease of patent quality. Commercial actors will undoubtedly strategically act in collusion to maximize the profit that can be derived from a patent so that they can then share that maximal profit between themselves. This is much better for the commercial entities than entering into competition where such rents will be naturally whittled

away for the public benefit. The American people deserve a patent system that is empowered with thorough and meaningful challenges to patents brought by competitors. Without such, try as they might to make their best decisions, the public will be forced to bear the burden of the PTO's continued inability to ensure that only deserving patents are issued. Thus, the Court of Appeals' decision permitting patentees to pay competitors to drop challenges to their patents is contrary to the substantial public interest in maintaining high patent quality, and should be reversed.

This Court has recognized that discouraging anticompetitive settlements of patent infringement cases has, in itself, a pro-competitive effect. Accused infringers who prove a patent invalid perform an important public service by correcting the PTO's errors on their own nickel. *See Lear v. Adkins*, 395 U.S. 653, 670 (1969) (explaining that if those "with economic incentive to challenge the patentability of an inventor's discovery" do not do so, "the public may continually be required to pay tribute to would be monopolists without need or justification"); *Pope Mfng. Co. v. Gormully*, 144 U.S. 224, 234 (1892) ("[i]t is as important to the public that competition should not be repressed by worthless patents as that the patentee of a really valuable invention should be protected in his monopoly"). Even those who try but fail to prove a patent invalid perform a public service by narrowing uncertainty as to the patent's validity, thus encouraging others to respect it. *Kloster Speedsteel*

AB v. Crucible, Inc., 793 F.2d 1565, 1581 (Fed. Cir. 1986).

Further, the Court of Appeals failed to recognize that application of sound antitrust law and policy comports with the policies implemented in the Hatch-Waxman Act. The entire point of Hatch-Waxman was to encourage and protect competition in the pharmaceutical industry, which it did in two principal ways: (i) making it easier for competition to already available products to be introduced; and (ii) encouraging new innovative products to be brought to market by strengthening patent rights. *See* H. Rep. No. 98-857(I). Unfortunately, pharmaceutical companies, both brand and generic, have been able to circumvent the pro-competitive intent of Hatch-Waxman to fashion a sharing of monopoly profits made by one of them instead of competing with one another in the marketplace because it is "littered with loopholes." Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227 (2001). By condoning net-anticompetitive gaming of the Hatch-Waxman regime through patent infringement litigation settlement agreements, the Court of Appeals' decision will frustrate, not promote, Hatch-Waxman's goals.

CONCLUSION

For the foregoing reasons, this Court should grant the petition for a writ of *certiorari*.

Respectfully submitted,

DANIEL B. RAVICHER
Counsel of Record
PUBLIC PATENT FOUNDATION, INC.
BENJAMIN N. CARDOZO SCHOOL OF LAW
55 Fifth Avenue, #928
New York, New York 10003
(212) 790-0442

Counsel for Amicus Curiae

January 7, 2011